No. 80-2182

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In The

Supreme Court of the United States

October Term, 1980

INWOOD LABORATORIES, INC., and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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QUESTIONS PRESENTED

1. Whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement?

2. Whether Section 32 of the Lanham Act (15 U.S.C. §1114) grants a trademark owner monopoly rights in the color of its product?

STATEMENT PURSUANT TO SUPREME COURT RULES 21 AND 28.1

The other parties to the proceeding in the court whose judgment is sought to be reviewed were appellees Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.

The parent company of petitioner Inwood Laboratories, Inc. is Forest Laboratories, Inc. Petitioner Premo Pharmaceutical Laboratories, Inc. is affiliated with Federal Pharmacal Co.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

OPINIONS BELOW

For convenience, the five opinions rendered below are set forth in the appendices in chronological order.

The first opinion of the District Court, denying respondent's request for preliminary injunctive relief on its primary claims is set forth in Appendix A, and has been officially reported at 455 F. Supp. 939 (E.D.N.Y. 1978)

(hereinafter referred to as *"IVES I"*). The Court of Appeals' decision affirming the District Court's denial of preliminary injunctive relief is set forth in Appendix B, and is officially reported at 601 F. 2d 631 (2d Cir. 1979) (hereinafter *"Ives II"*).

The second opinion of the District Court, dismissing respondent's complaint, is set forth in Appendix C, and is offically reported at 488 F. Supp. 394 (E.D.N.Y. 1980) (hereinafter *"Ives III"*). The opinion of the Court of Appeals at issue herein reversed the District Court and is set forth in Appendix D. It is officially reported at 638 F. 2d 538 (2d Cir. 1981) (hereinafter *"Ives IV"*). A subsequent order by the Court of Appeals denied petitioners' request for rehearing without opinion. The order is not officially reported, and a copy of this order is set forth in Appendix E. Acting on the mandate of the Court of Appeals, the District Court entered an order which, *inter alia*, enjoined petitioners from marketing a drug product in the same capsule colors as those sold by respondent. The memorandum and order are not yet officially reported, and copies are set forth in Appendix F (hereinafter *"Ives V"*).

JURISDICTION

The judgment of the United States Court of Appeals for the Second Circuit, sought to be reviewed herein, was entered on January 8, 1981. Petitioners' subsequent petition for rehearing with suggestion for rehearing *en banc* was denied on February 25, 1981. This Court granted petitioners' request for an extension of time within which to file the instant petition to and including June 25, 1981.

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The constitutional provisions involved herein are Article I, §8, clause 8 of the Constitution of the United States and the First Amendment to the Constitution of the United States. The federal statutory provisions involved herein are §§32 and 43(a) of the Lanham Act, 15 U.S.C. §§1114; 1125(a). The state statutory provisions involved herein are N.Y. Education Law §§6810; 6815(2)(h), (j); 6816; 6816-a (McKinney's Supp. 1981); and N.Y. Public Health Law §206(1)(o) (McKinney's Supp. 1981).

Due to the length of these provisions, they are all set forth in full in Appendix G.

STATEMENT OF THE CASE

At issue in this petition is a ruling by the Court of Appeals which imposes a severe chilling effect on petitioners' First Amendment free speech rights to advertise at the same time as it gives respondent an unprecedented monopolistic advantage. Specifically, the Second Circuit, has now held that manufacturers of generic pharmaceutical products, by reason of truthful comparative advertising and labeling for their products, become subject to liability for contributory infringement under the trademark laws of the United States. The Court of Appeals further held that by virtue of its trademark rights a large brand-name pharmaceutical manufacturer also obtains an automatic monopoly on the "trade dress" of its pharmaceutical products.[1]

1. Trade dress refers to the format one adopts for the packaging and labeling or appearance of goods, as distinguished from a trademark which refers to a name brand applied to the product. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232 (1964). *See also, Jean Patou, Inc. v. Jacqueline Cochran, Inc.*, 201 F. Supp. 861 (S.D.N.Y. 1962), *aff'd*, 312 F. 2d 125 (2d Cir. 1963).

This ruling, by its very nature, will have critical consequences for the future course of competition in the pharmaceutical industry and the further development of trademark law.

The basic underlying facts of the instant action are relatively simple. Respondent Ives Laboratories, Inc. ("Ives") has been marketing a drug ingredient identified chemically as cyclandelate for many years. Ives sells its cyclandelate product under the registered trademark "Cyclospasmol". Ives sells two dosage forms of this product: a 200-milligram version in a blue capsule, and a 400-milligram version in a blue/red capsule. The drug itself is a "peripheral vasodilator", which is primarily taken by elderly persons to produce an increase in blood flow and thereby inhibit the progressive conditions caused by certain vascular diseases. By law, cyclandelate may be dispensed only on the prescription of a physician. *See generally, Ives III* at 396 (54a).[2]

Until April 26, 1972, Ives had a monopoly on the sale of cyclandelate by virtue of its patent rights.[3] By 1976 however, petitioners Inwood and Premo, among others, had commenced marketing competitive generic equivalents of Ives' product. Petitioners are drug manufacturers who for the most part do not sell directly to dispensing pharmacists but rather to wholesale distributors and hospital pharmacies. Petitioners' generic products were marketed in the same dosage strengths and in the same capsule colors as the Ives product.

In selling their generic product in the same capsule colors as the formerly patented brand-name product, petitioners did not

2. All parenthetical references are to the pages of the attached Appendix, unless otherwise indicated.

3. The generic name "cyclandelate" was used in the United States before respondent used the name "Cyclospasmol" for its cyclandelate product. *See* Osol, Pratt & Altschule, *The United States Dispensatory*, 351 (26th Ed. 1968).

inaugurate a new practice. As expressly found by the District Court, the historic utilization of a similar appearance for generic pharmaceutical products is an important, if not critical, factor in the commercial ability of the generic manufacturers to compete with brand-name companies. *See Ives III* at 398-399 (63a-64a). In this case, the elements of the commercial need to utilize the same colors were found to consist of the following:

(1) Many patients, particularly elderly patients, associate the appearance of a medication with its therapeutic effect. Therefore, some patients refuse to accept equivalent drugs because of a difference in color.[4]

(2) Some patients eventually accept differences in color, but only after considerable anxiety and confusion caused by the change.

(3) Patients taking multiple medications often identify specific drugs by capsule color and follow their physicians' dispensing instructions by relying upon color. Changes in color

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4. As the District Court found:

> "The court finds the colors are functional in several respects. First, many elderly patients associate the appearance of their medication with its therapeutic effect. There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors. Other patients eventually accept equivalent drugs of a different appearance if their physician assures them that the prescription was filled correctly, but are caused considerable anxiety and confusion by the change. When patients associate the drug with its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage. *Thus color is an important ingredient in the commercial success of the product.*" *Id.* (63a). (Emphasis added.)

among different brands for the same product are thus a certain source of confusion, particularly for the elderly patient.

(4) Capsule color serves to distinguish multiple dosage strengths of the same ingredient.

(5) Uniform capsule color is an aid in drug identification in emergency situations. *See id.*

Because of the foregoing, some outlets for the dispensing of prescription drugs, particularly hospitals, refuse to purchase equivalent generic products in different colors because of the confusion and anxiety it may cause for patients.[5]

After the appearance of petitioners' generic cyclandelate in the market, New York State, in 1977, enacted what is commonly known as a "drug substitution law". *See* N.Y. Educ. Law, §§6810, 6816, 6816-a (McKinney's Supp. 1981) (121a). This statute and its implications for competition in the pharmaceutical industry provide a critical setting for the issues raised in this case. Under the new statute, the sale of lower-priced generic equivalents is encouraged as a matter of public policy by altering the traditional practice under which a pharmacist is required to dispense a particular brand name if that name is specified on a prescription.

Recognizing that many physicians know drugs only by their brand name and not by the generic name, the statute directs that

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5. "The functional aspect of the color of the capsules is further evidenced by the fact that the parent of Inwood discontinued sale of cyclandelate in a green color because the different color was not accepted by hospitals, pharmacies and wholesalers in the light of the potential for confusion. One hospital official testified that he refused to purchase cyclandelate in a green capsule." *Id.* at 399 (63a-64a).

pharmacists may (and in most cases must) supply a lower-cost generic product, even if a brand-name is specified. This is so unless the doctor indicates on a special line of the prescription form that only the brand-name product is to be dispensed. *See generally, Pharmaceutical Society of State of New York v. Lefkowitz*, 586 F. 2d 953 (2d Cir. 1978). The purpose of New York's generic substitution law undeniably reflects a commitment to generic prescribing and encouraging the use of low-cost generics by the consuming public. *Id.* at 957.

Petitioners' cyclandelate products are equivalent to Ives' Cyclospasmol product. Under the law of New York State, petitioners' cyclandelate may be substituted for respondent's product if the physician has not barred such substitution on the prescription form. *See* N.Y. Educ. Law, §6810(6) (McKinney's Supp. 1981) (114a). As this Court has pointed out, it is very well known that drug prices vary widely, *see Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763-764 (1976); and generic companies afford the consumer significant savings in the cost of drug products. Petitioners do in fact offer their cyclandelate products to customers at a "substantially lower price" than that charged for the Ives "Cyclospasmol" brand. *Ives IV* at 541 (76a).

Since forty-eight states, the District of Columbia and Puerto Rico have adopted a generic substitution law,[6] the prospect of patient resistance to color changes is now of even greater significance than ever before. If brand-name companies are granted a monopoly on the color of their pharmaceutical products, patient resistance to color changes, while perhaps aiding brand-name companies, will serve to impede and perhaps

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6. *See Competition in the Drug Industry: Hearings Before the Subcomm. on Oversight & Investigations of the House Comm. on Energy and Commerce*, 13, 91 Cong., 1st Sess. (March 10, 1981).

frustrate the economic savings sought to be encouraged by the drug substitution legislation. The District Court expressly so found. *See Ives III*, 488 F. Supp. at 401-02 (69a).

On the eve of the effective date of the landmark New York drug substitution law, Ives commenced the instant case. Ives sought to prohibit petitioners from continuing their then almost two-year-old practice of utilizing the familiar blue and blue/red colors for their cyclandelate capsules. *See Ives I* at 943 (5a). Ives' complaint asserted, *inter alia*, that petitioners' marketing of these capsule colors was actionable under both federal and state law as "unfair competition". Jurisdiction of the District Court was based on 28 U.S.C. §§1331(a), 1338(a) and (b). *See Ives I* at 942 (5a).

Ives first sought a preliminary injunction on the grounds that petitioners' use of the identical capsule colors constituted a false description or designation of origin within the meaning of §43(a) of the Lanham Act, 15 U.S.C. §1125(a), and that it violated the New York State law of unfair competition. Ives further claimed that petitioners were liable for "contributory trademark infringement". Except in a minor respect not at issue herein, the District Court denied the motion for preliminary injunction. *See Ives I* (27a).

On appeal, the Second Circuit affirmed the denial of the preliminary injunction. Judge Friendly found that, in view of the evidence of functionality of color produced below and Ives' failure to demonstrate any secondary meaning for its capsule colors, Ives had not sufficiently made out a case for unfair competition under either state or federal law to support the entry of an injunction. *See Ives II* (28a).

On the question of contributory trademark infringement, Ives' proof was limited to only 15 instances of improper

substitution of cyclandelate for Cyclospasmol.[7] Accordingly, the Second Circuit found that these 15 instances, which were restricted to pharmacists who had a "proclivity toward illegal substitution," *see Ives I* at 950 (24a), were not sufficient to render petitioners contributorily liable for the alleged trademark infringement which had occurred.[8] The court also noted that "discovery and trial might show that the practice was much more widespread, or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Ives II* at 644 (53a).

For the subsequent trial, Ives conducted an extensive

7. Improper substitution is akin to the tort of "passing off". In the context of prescription pharmaceuticals under New York State law, it occurs when a doctor prescribes the brand-name product and signs the prescription form "dispense as written". Thereafter, when the patient presents the prescription to the druggist, the druggist commits improper substitution and a criminal offense if he or she fills the prescription with a product which is not the product specifically requested by the physician. Trademark infringement may occur if the druggist affixes a company's trademark name to the label of the container which does not contain the trademarked product. *See generally*, N.Y. Educ. Law, §§6810, 6815(2)(h), (j); 6816, 6816-a (McKinney's Supp. 1981); and N.Y. Pub. Health Law, §206(1)(o) (McKinney's Supp. 1981) (112a-122a). The Cyclospasmol name appeared on the product in 12 out of 15 instances noted above.

8. Traditionally, the judicial doctrine of contributory trademark infringement, which has been read into §32 of the Lanham Act, requires a wilful participation or assent, even if only by implication, in another party's acts of trademark infringement. *See Ives II* at 636 (35a); *Coca-Cola Co. v. Snow Crest Beverages*, 64 F. Supp. 980, 999 (D. Mass. 1946), *aff'd*, 162 F. 2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947). Since petitioners were not shown to have any knowledge of these 15 "bad actors", the Second Circuit agreed that petitioners could not be liable as contributory infringers on this evidence. Additionally, the Court of Appeals pointed out that:

> "the judge was right in concluding that the protection conferred by . . . section [32] is *narrower* than that afforded by §43(a) . . ." *Id.* (34a) (emphasis added).

nationwide survey involving 12,000 physicians attempting to establish that its capsule colors had a secondary meaning,[9] as required by §43(a) of the Lanham Act. Additionally (and ultimately of critical importance), Ives conducted a survey of 83 pharmacists, limited to New York State, to evaluate the process by which cyclandelate products were being lawfully substituted under the New York State drug substitution law.

The latter survey found that in a total of 10 instances the pharmacist who was authorized to substitute a generic cyclandelate product had done so, but had not fully complied with the labeling requirements of the law. *See N.Y. Educ. Law*, §6816 (McKinney's Supp. 1981) (112a). Nine of the ten druggists orally advised the patient that they were dispensing the generic drug. Five of the ten also wrote on the product label the word "generic", or its abbreviation, before or after the name "Cyclospasmol". In only one instance was the product labeled "Cyclospasmol" without any written or oral indication of generic status. Most significantly, the evidence showed only one instance out of the 83 test shoppings where a patient was charged the brand-name price for a generic product. *See Ives III* at 397-398 (60a).

In a comprehensive opinion, the District Court, after a bench trial, denied all of Ives' claims for relief against petitioners. The court found that to give Ives a monopoly of capsule colors would severely inhibit the purposes of the New York drug substitution law, because the colors served very significant functional purposes. *Ives III* at 401-402 (69a). *See also, Ives II* at 644 (52a). The court further found that Ives had not established that it was entitled to a monopoly over the colors blue and blue/red since the colors had not achieved any secondary meaning. In addition, it held that petitioners were not

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9. This attempt was unsuccessful, as discussed *infra*.

liable for contributory trademark infringement under §32 of the Lanham Act since they did not continue to sell their generic drugs to pharmacists whom they knew, or had reason to know, were engaging in trademark infringement of Ives' Cyclospasmol mark. *Ives III* at 397 (59a).

Upon the second appeal, however, the Second Circuit reversed in a split opinion, reaching only the question of contributory trademark infringement, without addressing the other issues in the case relating to §43(a) of the Lanham Act and the state law of unfair competition.[10]

The majority opinion in *Ives IV* acknowledged that there was no additional evidence of improper substitution produced by Ives, and that the original evidence of improper substitution was not sufficient to establish contributory trademark infringement. Rather, the majority focused upon Ives' additional evidence which showed instances wherein a druggist, who was authorized to substitute the generic drug (cyclandelate), affixed the word "Cyclospasmol" on the label of the dispensing container for such capsules, together with either the word or symbol indicating that it was a generic product, or an oral explanation that the generic product was being dispensed. The Second Circuit held that pharmacists who labeled the products dispensed as "generic Cyclospasmol" were guilty of trademark infringement. Petitioners were found to be contributorily liable for such infringement because petitioners had used catalogs and

10. Despite the District Court's extensive finding discussed earlier as to functionality of color, the Court of Appeals declared only that these legitimate reasons for using lookalike capsules were "unconvincing", *Ives IV* at 544 (85a). As Judge Mulligan (the only judge who sat on both Court of Appeals panels) noted in his dissenting opinion, the "majority does not characterize this finding or other evidence of functionality discussed in the opinion below as 'clearly erroneous' . . . Judge Nickerson's findings of fact based upon the testimony of witnesses who appeared before him cannot be disregarded by this court." *Id.* at 547 (91a) (footnote omitted).

price sheets to advertise their products to drug wholesalers and hospital purchasing agents. The catalogs and price sheets provided comparisons of the wholesale price for the brand-name, in contrast to that of the generic product, and in some instances had identified their respective color configuration.[11] The Court of Appeals held that these ten instances were sufficient to establish liability for contributory trademark infringement, even though petitioners Inwood and Premo herein were not shown to have distributed any of their price sheets or catalogs to the pharmacists who allegedly committed the trademark infringement.[12]

The ruling of the Second Circuit holds for the first time that describing a drug product as a generic version of a trademarked item constitutes trademark infringement. Petitioners were held liable for such a description by pharmacists, to whom they do not even sell directly, under the further theory that, in view of petitioners' comparative advertising to their wholesale accounts, petitioners should have known that pharmacists who bought from the wholesalers "might" label their products as a generic version of the trademarked item. While the reasoning involved in reaching this conclusion is unclear,[13] the majority found that

11. In contrast to petitioners' marketing practices, Ives spent more than $10,000,000 in promotional and advertising expenses in detailing its products by having salesmen make personal visits to physicians, distributing samples and promotional materials. *See Ives III* at 396 (57a).

12. It is clear from the *Ives IV* opinion that these instances were considered trademark infringement on the part of pharmacists and that this was the evidence which was critical to the Court of Appeals' finding that petitioners were liable for contributory trademark infringement. *See Ives IV* at 542-543 (82a) ["The additional evidence introduced by Ives at trial was *clearly sufficient* to establish a §32 violation." (emphasis added).]

13. As one legal commentator recently observed:

> "Perhaps one's expectations must necessarily be limited, but the level of analysis in the recent colour get-up judgments

(Cont'd)

the brand-name company must be granted the perpetual, exclusive right to use the capsule colors in question.[14]

(Cont'd)

has fallen extra-ordinarily low. The courts seem to be indulging in non-sequiturs, fits of pique, and bizarre overreactions, instead of making measured, rational, dispassionate responses to whatever problems there are in resolving these business conflicts. *Moreover, the distribution of what seems to be error and mistake is now quite unrandom; there has been a definite tilt in favour of the brand name drug companies, against the generic sellers.* One would not think this to be one of the great political issues of the times; that distorts perception and judicial impartiality. Yet the courts seem to be reacting to generic sellers as if they were trying to subvert Government. Why the courts are doing so seems inexplicable in terms of ordinary common law legal analysis methods based on the categories of trade mark and unfair competition law as they have been developed in regard to other products. Something may be going on in these cases that is not reflected in the lines of the courts' published opinions. To predict these judgments is now simple, for the same side always wins. To understand the judgments, perhaps, use of a different discipline is required." *See* R.H. Stern, *The Persantine, Librax & Elavil Decisions: Colourful Brands of Drugs*, 2 Eur. Intel. Prop. Rev. 59 (1981). *See also*, 3 R. Callman, *Unfair Competition* §82.1(m) at 171-180 (Cumm. Supp. 1979).

14. The decision of the Second Circuit:

". . . [requires the] grant [of] a permanent injunction giving plaintiff a monopoly over the colors blue and a combination of blue and red for capsules of the same shape and size as those used by plaintiff to sell Cyclospasmol." *See Ives V* at 2 (98a).

REASONS FOR GRANTING THE WRIT

I.

Certiorari should be granted to determine whether the Second Circuit properly held that truthful comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement.

The Second Circuit, by its ruling, has effected a radical change in the law of trademarks which threatens the entire concept of comparative trademark advertising. Petitioners were held contributorily liable for the acts of a pharmacist in labeling of cyclandelate products. The critical element in finding this contributory trademark infringement liability was the "additional evidence" by which Ives showed that some pharmacists, while lawfully substituting a generic product under the New York drug substitution law, had labeled or described the product as "generic Cyclospasmol," either orally or in writing. Never before has any court held that the mere description of one product as a generic equivalent of a trademarked product constitutes trademark infringement under the Lanham Act.

To state, as occured here, that a product is "generic Cyclospasmol" clearly indicates that it is not the trademarked product, but rather, a generic version thereof. Yet without any explanation, the Second Circuit has held that such acts constituted trademark infringement by the pharmacist.[15]

Similarly, in finding petitioners contributorily liable for this supposed trademark infringement, the court held that liability

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15. If these acts had not constituted trademark infringement, petitioners would, of course, not have been found liable for contributory trademark infringement.

was triggered by petitioners' exercise of their commercial free speech rights. Such speech took the form of brochures and price lists which utilized comparative advertising. The price paid by petitioners for the exercise of this right to advertise was the finding of liability for contributory trademark infringement, and an injunction against the use of a critical, competitive product feature — the blue and blue/red colors.

Justice Holmes, speaking for this Court in 1910, established the basic principle that a competitive product may be labeled with specific reference to the trademark of another product without invoking liability for trademark infringement:

> "The real intent of the plaintiff's bill, it seems to us, is to extend the monopoly of such trademark or trade name as she may have to a monopoly of her type of bitter water, by preventing manufacturers from telling the public in a way that will be understood what they are copying and trying to sell. But the plaintiff has no patent for the water, and the defendants have a right to reproduce it as nearly as they can. They have a right to tell the public what they are doing and to get whatever share they can in the popularity of the water by advertising that they are trying to make the same article and think that they succeed. . . . By doing so they are not trying to get the good will of the name, but the good will of the goods." *Saxlehner v. Wagner*, 216 U.S. 375, 380 (1910).

In the instant case, the notation of the term "generic" on the capsule container, or the pharmacist's orally informing the patients that they were receiving the generic product (although

labeled as "Cyclospasmol"),[16] excluded the notion that the pharmacist was selling Ives' goods. Thus, the critical facts supporting application of the rationale of contributory infringement were lacking in the instant case. With respect to the "additional evidence" adduced by Ives, patients knew that they were not getting the "trademarked" goods, and they were not charged the higher price usually applicable for the "trademarked" item. Based on the clear precedent prior to *Ives IV*, this use of the written and oral term "generic Cyclospasmol" or "same as Cyclospasmol" or "equivalent to Cyclospasmol" was not an infringement of the Cyclospasmol trademark. *See Champion Spark Plug Co. v. Sanders*, 331 U.S. 125, 129-130 (1947); *Prestonettes, Inc. v. Coty*, 264 U.S. 359, 368-369 (1924); *Societe Comptoir de L'Indus., etc. v. Alexander's Dep't Stores*, 299 F. 2d 33 (2d Cir. 1962); *Taylor Instrument Companies v. Fawley-Brost Co.*, 139 F. 2d 98, 101 (7th Cir. 1943), *cert. denied*, 321 U.S. 785 (1944); *Electric Auto-Lite Co. v. P&D Mfg. Co.*, 78 F. 2d 700 (2d Cir. 1935), *cert. denied*, 296 U.S. 648 (1936); *Geisel v. Poynter Products*, 295 F. Supp. 331 (S.D.N.Y. 1968). *Accord, Smith v. Chanel, Inc.*, 402 F. 2d 562 (9th Cir. 1968); *Viavi Co. v. Vimedia Co.*, 245 F. 289 (8th Cir. 1917), *cert. denied*, 246 U.S. 664 (1918).

The legal commentators have distilled the concepts expressed in these cases into what, until the *Ives IV* decision, was a basic and universally recognized tenet of trademark law:

> "[t]he law is that it is neither trademark infringement nor unfair competition to truthfully compare competing products in advertising, and in doing so, to identify by trademark, the competitor's goods. . . . An analogous situation

16. Oral explanations are clearly sufficient and in fact have sometimes been required to avoid liability for trademark infringement. *See, e.g., Coca-Cola Co. v. Dorris*, 311 F. Supp. 287, 292 (E.D. Ark. 1970).

> is that in which a seller has attempted to copy a public domain feature of a competitor's product. Is the legal copier free to tell the buyer of the close identity between the products? *If a seller has the right to copy public domain features of his competitor's goods, then, as a corollary, he must have the right to inform the public of this fact.* If legal imitation is the 'life-blood of competition,' *then the imitator who sells a cheaper version of the original is entitled to so inform the public.*" J.T. McCarthy, *Trademarks and Unfair Competition,* §25.14 at 192 (1973) (emphasis added).

The appellate court's disregard of this basic right to competitive, comparative use of a trademark name takes on even more ominous ramifications when the asserted rationale for the finding of *contributory* trademark infringement is considered. Petitioners Inwood and Premo, who do not, for the most part, sell or advertise directly to retail pharmacists were held contributorily liable for the supposed retail pharmacist infringement, at least in significant part, because petitioners had engaged in comparative advertising to their wholesaler accounts.[17]

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17. The court observed:

> "Ives contends that appellees violated §32 of the Lanham Act because of their deliberate use of lookalike capsules *and pro-substitution catalogues* encouraged retail druggists to substitute generic cyclandelate illegally for CYCLOSPASMOL." *Ives IV* at 541 (76a) (emphasis added).
>
> "By using capsules of identical color, size, and shape *together with a catalog describing their appearance and*

(Cont'd)

The Second Circuit holding has placed any company who comparatively advertises on the horns of a dilemma. If it chooses to engage in comparative advertising, it runs the risk that, under the Second Circuit opinion, it may be automatically liable for contributory trademark infringement and thereby lose the right to *market an important functional and competitive feature of* its *product.* If it chooses not to comparatively advertise under this threat of liability, then as against it the competitor's trademark (as Justice Holmes observed) has been impermissibly extended to the product itself. *See Saxlehner v. Wagner,* 216 U.S. at 380.

In addition to being at odds with the clear spirit of the principle ". . . that use of another's trademark to identify the trademark owner's product in comparative advertising is not prohibited by either statutory or common law . . . ,"[18] the *Ives IV* decision conflicts with the current holdings of this Court concerning the right to commercial free speech. *See e.g., Bates v. State Bar of Arizona,* 433 U.S. 350 (1977).

The Second Circuit has taken petitioners' legitimate exercise of their First Amendment right to comparatively advertise and found that such exercise is punishable by becoming subject to an injunction on the use of a competitive color, under the judicial doctrine of contributory trademark infringement. The First

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(Cont'd)

> *listing comparative prices of CYCLOSPASMOL and generic cylandelate,* appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists, be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage." *Id.* at 543 (83a) (emphasis added).

18. *Smith v. Chanel, Inc.,* 402 F. 2d at 565.

Amendment right to free speech cannot be so cavalierly stifled and chilled. The Second Circuit failed to engage in any type of balancing test in order to ascertain whether such liability was constitutionally permissible or necessary.

As this Court noted in *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. at 763-764, in striking down a prohibition of prescription drug advertising:

> "When drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities."

In recognition of this Court's affirmation of the right to commercial free speech, other courts have recognized that the Lanham Act should not be construed in a manner that would bring it into conflict with First Amendment interests. *Stop the Olympic Prison v. U.S. Olympic Committee*, 489 F. Supp. 1112, 1124 (S.D.N.Y. 1980). *See also, Triangle Publications, Inc. v. Knight-Ridder Newspapers, Inc.*, 445 F. Supp. 875, 884 (S.D. Fla. 1978), *aff'd on other grounds*, 626 F. 2d 1171 (5th Cir. 1980) (court observed that comparative advertising which uses another's trade name "is in harmony with the fundamental objectives of free speech and free enterprise in a free society."); *Fur Information and Fashion Council v. E.F. Timme & Son, Inc.*, 364 F. Supp. 16, 22 (S.D.N.Y. 1973), *aff'd on other grounds*, 501 F. 2d 1048 (2d Cir.), *cert. denied*, 419 U.S. 1022 (1974).

Here the Second Circuit has penalized both the label statement of generic equivalence and the advertisement of comparative availability without considering the limitations which the First Amendment places on judicial interference

with the process of communicating essential competitive information. It is respectfully submitted that, in view of the far-reaching consequences of *Ives IV*, so drastic an alteration in traditional concepts of trademark law, which alteration also impinges on basic First Amendment rights, should not be permitted to take effect without the benefit of full scrutiny by this Court by way of certiorari, as requested herein.

II.

Certiorari should be granted to determine whether the Second Circuit properly held that Section 32 of the Lanham Act (15 U.S.C. §1114) grants a trademark owner monopoly rights in the color of its product.

The ruling by the Court of Appeals automatically vests in the owner of every trademark an accompanying anti-competitive right in the color or trade dress of its product. Under the Second Circuit's reasoning, every time a competitor imitates color or trade dress, he might "reasonably anticipate" that someone in the chain of distribution might either intentionally or accidentally misapply the wrong trademark to the goods in question. Since this will always be true, every trademark would necessarily carry with it an absolute right to the trade dress or color in question.

In so ruling, the Court of Appeals has radically altered existing law as to the protection which can be afforded to trade dress or color. Heretofore, if trade dress or color included functional features, no monopoly rights could be obtained outside the patent laws. Yet in the face of comprehensive findings of functionality by the District Court, the Court of Appeals grants monopoly rights under the rubric of supposed liability for contributory trademark infringement.

Previously, the issue of whether or not the color of prescription pharmaceuticals could be copied by a subsequent manufacturer has been determined under the law of trade dress, under §43(a) of the Lanham Act, 15 U.S.C. §1125(a), or the applicable state law of unfair competition. Courts have denied proprietary rights to color unless the color was shown to be non-functional. *See e.g., William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924). *But cf., SK&F v. Premo Pharmaceutical Laboratories, Inc.*, 625 F. 2d 1055 (3d Cir. 1980). In addition, the courts have required a distinct showing of secondary meaning before proprietary rights could be obtained. *See, e.g., Upjohn Co. v. Schwartz*, 246 F. 2d 254 (2d Cir. 1957).

In this action, all of the traditional factors were determined in favor of petitioners' right to use the colors in question. The District Court found that the colors were functional, and that in any event no secondary meaning had been established. It thus rejected Ives' claim of an exclusive right to the specific color configurations. The Court of Appeals, however, in a departure from all prior precedent in this area of law, found that a company may have certain types of proprietary color rights by virtue of the trademark laws of the United States.

The above *Ives IV* determination is contrary to two well-established principles. First, color itself, which is not impressed upon an arbitrary design, nor employed in association with characteristics which would serve to distinguish the article as made and sold by a particular company, does not constitute a valid trademark, and is not entitled to protectible status, absent other evidence of unfair competition. *A. Leschen & Sons Rope Co. v. Broderick & Bascom Rope Co.*, 201 U.S. 166 (1906). *See also, Coats v. Merrick Thread Co.*, 149 U.S. 562 (1893).

The plain blue and blue/red colors of respondents' drug capsules are not part of an arbitrary design, nor did they

indicate any "secondary meaning". Therefore, the decision of the Court of Appeals flies in the face of a long series of historical decisions which explicitly state that color can be neither trademarked nor monopolized. *See Norwich Pharmacal Co. v. Sterling Drug Inc.*, 271 F. 2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); *Tas-T-Nut Co. v. Variety Nut & Date Co.*, 245 F. 2d 3 (6th Cir. 1957); *Campbell Soup Co. v. Armour & Co.*, 175 F. 2d 795 (3d Cir.), *cert. denied*, 338 U.S. 847 (1949); *Newcomer & Lewis v. Scriven Co.*, 168 F. 621, 623 (6th Cir. 1909); *Diamond Match Co. v. Saginaw Match Co.*, 142 F. 727 (6th Cir. 1906). *See also, Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd.*, 604 F. 2d 200, 204, n.6 (2d Cir. 1979); *Plastilite Corp. v. Kassnar Imports*, 508 F. 2d 824 (C.C.P.A. 1975); *In re Shaw*, 184 U.S.P.Q. 253 (T.T.A.B. 1974); *American Basketball Assoc. v. A.M.F. Voit, Inc.*, 358 F. Supp. 981 (S.D.N.Y.), *aff'd without opinion*, 487 F. 2d 1393 (2d Cir. 1973), *cert. denied*, 416 U.S. 986 (1974).

Second, the decision of the Court of Appeals runs afoul of this Court's classic determination that freedom to copy the unpatented wares of a competitor is critical to a competitive economy.

In *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964), and in *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), this Court ruled that once an article is no longer entitled to protection under the federal patent laws, or is not covered by a federal trademark, the public is entitled to share in its goodwill, and thus it may be copied exactly.

> "To forbid copying would interfere with the federal policy, found in Art. I, §8, cl.8 of the Constitution and in the implementing federal statutes, of allowing free access to copy whatever the federal patent and copyright laws leave in the public domain." *Id.*

To hold otherwise, the Court ruled, would be to extend the patent monopoly beyond that contained in the patent. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. at 230. As this Court noted in *Compco:*

> "That an article copied from an unpatented article could be made in some other way, that the design is 'non-functional' and not essential to the use of either article, that the configuration of the article copied may have a 'secondary meaning' which identifies the maker to the trade, or that there may be 'confusion' among purchasers as to which article is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling; however, and regardless of the copier's motives, *neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling.*" 376 U.S. at 238 (emphasis added).

See also, American Safety Table Co. v. Schreiber, 269 F. 2d 255, 272 (2d Cir. 1959).

As a corollary to this principle, this Court has established that, even in the face of a finding of trademark infringement, the relief as ordered by the Court of Appeals in this case is impermissible. Rather, prophylactic requirements, such as labeling, that eliminate or minimize any confusion as to source that may result from imitation protect the originator's interest in identification of source, while permitting competitors to market its product "in the form in which the public has become accustomed to see the article." *See Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120 (1938).

This limitation was first set forth in this Court's decision in *William R. Warner & Co. v. Eli Lilly Co., supra,* which enunciated the proper limitations on the scope of relief that should have been applied to the instant case:

> "Nevertheless, the right to which respondent is entitled is that of being protected against unfair competition, not of having the aid of a decree to create or support, or assist in creating or supporting, monopoly of the sale of a preparation which everyone, including petitioner, is free to make and vend. The legal wrong does not consist in the mere use of chocolate as an ingredient, but in the unfair and fraudulent advantage which is taken of such use to pass off the product as that of respondent. *The use dis-associated from the fraud is entirely lawful, and it is against the fraud that the injunction lies.* But respondent being entitled to relief, is entitled to effective relief; . . . Clearly, the relief should extend far enough to enjoin petitioner, and its various agents, from, directly or indirectly, representing or suggesting to its customers the feasibility or possibility of passing off Quin-Coco for Coco-Quinine. *The Court of Appeals held that petitioner should be unconditionally enjoined from the use of chocolate. We think this goes too far.* [As] an effective remedy, we think the decree fairly may require that the original packages sold to druggists shall not only bear labels clearly distinguishing petitioner's bottled product from the bottled product of respondent, but that these labels shall state affirmatively that the preparation is not to be sold or dispensed as Coco-Quinine or be used in filling prescriptions

> or orders calling for the latter." *William R. Warner & Co. v. Eli Lilly Co.*, 265 U.S. at 532-533.

See also, Coca-Cola Co. v. The Koke Company of America, 254 U.S. 143 (1920) (court refused to allow injunction prohibiting use of cola coloring in trademark infringement action).[19]

The holding of the Second Circuit, which prohibits color copying, "*goes too far.*"[20] As this Court determined in *Lilly*, the use of plaintiff's colors by defendant *disassociated* from the fraud of passing off or mislabeling is *lawful*, and it is against the fraud which the injunction must issue. *Accord, Upjohn Co. v. Schwartz, supra;* and *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F. 2d 725, 730-731 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946).

This critical distinction was ignored by the Court of Appeals. Rather, Judge Mansfield stated that a prohibition upon the copying of the unpatentable, untrademarkable colors of Cyclospasmol was necessary, since:

> "*it would . . . give Ives the protection to which it is entitled to for its trademarked product.*" *Ives IV* at 545 (86a) (emphasis added).

Petitioners respectfully submit that this statement is contrary to the law of trademarks, as it has been interpreted by

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19. In *Coca-Cola*, Justice Holmes noted that "the product[,] including the coloring matter[,] is free to all who can make it if no extrinsic deceiving element is present." *Id.* at 147.

20. The court justified it only on the grounds that an injunction was the "simplest" way to protect respondent. *Ives IV* at 545 (86a).

this Court since the turn of the century. The rights granted by the trademark laws to protect a name do not include the coloration of the trademarked product.

Ives IV accomplishes the opposite result by applying a *per se* rule in order to find liability for contributory trademark infringement. Under the Second Circuit's standard, the mere sale of a similar-looking product is enough to satisfy the intent requirement inherent in a finding of contributory trademark infringement.[21] Even more crucial is the fact that there was no evidence that look-alike capsules actually encouraged or assisted or facilitated the alleged mislabeling.

As a result of the new rule of law established by the Second Circuit, the owner of the trademark can now fully monopolize its trade dress. Such a decision runs counter to Congress' intent in adopting §32 and to this Court's analysis of the law of permissible copying Trademarks can now be used as patent substitutes or to further perpetuate product monopolies. The Second Circuit decision has turned the law of trademarks on its head: because of the functional nature of color, fully effective competition will be severely limited in the manufacture and sale of generic drugs. *Cf. International Order of Job's Daughters v. Lindeburg & Co.*, 633 F. 2d 912, 917-920 (9th Cir. 1980), *cert. denied*, 49 U.S.L.W. 3931 (June 15, 1981).

If the opinion of the Second Circuit is not overturned,

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21. It should be emphasized that, as Judge Mulligan pointed out in his dissent, "there is not a scintilla of evidence to suggest that the defendants sold to those pharmacies knowing or having reason to believe that illegal substitution or mislabelling had occurred." *Ives IV* at 546 (87a). The latest rule in the Second Circuit thus is also inconsistent with the standards established by both Judge Friendly in *Ives II* and by Judge Wyzanski in his leading opinion of *Coca-Cola Co. v. Snow Crest Beverages, supra.*

brand-name companies will be able to utilize §32 to extend incidents of their patent monopolies by automatically prohibiting generic companies from marketing their products in the appearance to which the public has grown accustomed. We respectfully urge this Court to recognize that the monopolization of color rights sanctioned by the Second Circuit portends a serious threat to effective competition in trademarked items, in general, and pharmaceutical products, in particular. Certiorari is urgently needed to resolve these issues of vital importance to the public.

CONCLUSION

It is respectfully requested that a writ of certiorari issue to review the judgment of the United States Court of Appeals.

Respectfully submitted,

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APPENDIX A — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 455 F. SUPP. 939 (E.D.N.Y. 1978)

United States District Court
E. D. New York
No. 78 C 372

Aug. 2, 1978.

IVES LABORATORIES, INC.,

Plaintiff,

v.

DARBY DRUG CO., INC., Inwood Laboratories Incorporated, Lowitt Laboratories, Inc., MD Pharmaceutical Company, Inc., Premo Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.,

Defendants.

Egon E. Berg, New York City, and Rogers, Hoge & Hills, New York City, for plaintiff; Vito V. Bellino, Mortimer Altin, Steven J. Baron, William F. Weigel, Marie Driscoll, Charles J. Raubicheck, of counsel.

Salon, Bloustein & Raybin, New York City (Robert V. Marrow, New York City, of counsel), for defendants Darby, Rugby, Sherry, & MD.

Kirschstein, Kirschstein, Ottinger & Cobrin, P.C., New York City (Peter T. Cobrin, New York City, of counsel), for defendant Premo Pharmaceutical.

Appendix A

Bass Ullman & Lustigman, New York City (Sheldon S. Lustigman, New York City, of counsel) for defendant Inwood Laboratories.

OPINION

NICKERSON, District Judge.

Plaintiff Ives Laboratories, Inc. ("Ives"), which manufactures and sells under the registered trademark "Cyclospasmol" a prescription drug of the generic name of "cyclandelate", brought this suit against defendants under the Trademark Act of 1946, as amended, (known as the "Lanham Act"), 15 U.S.C. §§1051ff., for trademark infringement and false designation of the origin of, and false description of, goods in commerce, and under New York common and statutory law for unfair competition. Plaintiff moves for an order preliminarily enjoining defendants from (1) using the trademark "Cyclospasmol" or any word confusingly similar including "Spasmol", (2) manufacturing and selling generic cyclandelate in capsules which are blue, red or a combination of blue and red, and (3) continuing other alleged acts of unfair competition.

I

Since 1958 plaintiff Ives, a New York corporation, and its predecessors and parent company American Home Products Corporation have sold cyclandelate under the registered trademark "Cyclospasmol". The drug is so-called peripheral vasodilator said to produce an increase in blood flow and is administered not to cure but to inhibit the progressive and debilitating conditions caused by certain vascular diseases, generally in the aged. Its use is therefore long term, for most patients a lifetime.

Appendix A

Before the expiry date on April 26, 1972 of a patent protecting cyclandelate plaintiff or its predecessors had the exclusive right to sell the drug in the United States. Commencing in 1962 plaintiff has market dosages of 200mg. in a pale blue capsule having an imprint reading "Ives 4124". Since 1975 plaintiff has sold 400mg. dosages in a red and blue capsule with the imprint "Ives 4148". Plaintiff has directed its extensive advertising and promotion of "Cyclospasmol" primarily to physicians. In addition, on personal visits to doctors plaintiff's representatives have distributed more than two million "starter" samples. Some one hundred and twenty five million of the 200mg. and 400mg. capsules have been sold since 1962. Over the past ten years such sales have exceeded $65,000,000.

Defendants are three drug manufacturers, three wholesalers, and one retail pharmacy. The three manufacturers, Premo Pharmaceutical Company, Inc. ("Premo"), Inwood Laboratories, Incorporated ("Inwood"), and MD Pharmaceutical Company, Inc. ("MD"), purchase cyclandelate powder and empty capsules and fill and sell them as generic cyclandelate to wholesalers, hospitals, retail pharmacies and others.

Premo and Inwood, both New York corporations, and MD, a California corporation, distribute 200mg. capsules of a pale blue color identical or very similar to that used by plaintiff. Premo and Inwood also distribute 400mg. capsules identical or very similar in colors to plaintiff's 400mg. capsules. Until recently none of the capsules distributed by the manufacturers bore any name or other identification. On June 26, 1978 Premo filed an affidavit stating that it in the future would imprint "Premo" on its capsules and had discontinued using unmarked capsules.

Appendix A

The three wholesalers, Darby Drug Co., Inc. ("Darby"), Rugby Laboratories, Inc. ("Rugby"), and Sherry Pharmaceutical Co., Inc. ("Sherry") all New York corporations, are now under common ownership and management. They purchase generic cyclandelate capsules and resell them to wholesalers, doctors, pharmacies and others.

The manufacturers and the wholesalers promote the generic product as "comparable" or "similar" or "equivalent" to "Cyclospasmol". In some catalogs they refer to the color of the capsules. For purposes of the motion it is conceded that the cyclandelate sold by defendants has the same bioavailability as "Cyclospasmol" and that the two are bioequivalent, meaning that the therapeutic ingredients in both have an equivalent effect.

Recently Sherry, which had offered the drug under the name "Spasmol", abandoned that name. The other defendants have not sold under a brand name.

Defendant Lowitt Labs Inc. ("Lowitt"), a New York corporation, is a retail pharmacy. The complaint alleges that on receiving a prescription for "Cyclospasmol" Lowitt substituted generic cyclandelate and labelled the prescription bottle "Cyclospasmol". On consent the court entered a decree enjoining Lowitt from substituting cyclandelate from another source as plaintiff's "Cyclospasmol" and from using that trademark or one so similar as to be likely to cause confusion. The claim against Lowitt is thus not at issue, and the remaining defendants will be called "the defendants".

Appendix A

II

Plaintiff makes various contentions under both federal and New York State law. Plaintiff's first claim is under Section 32 of the Lanham Act, 15 U.S.C. §1114(1)(a), which imposes liability for the use of a copy or colorable imitation of a registered mark in selling, distributing or advertising of goods where the use is likely to deceive or cause confusion or mistake. Plaintiff asserts two kinds of violation of this section: (1) that Sherry infringed the "Cyclospasmol" mark by using the name "Spasmol" and (2) that the defendants have been guilty of "contributory infringement" of the "Cyclospasmol" mark. The latter claim is based on the assertion that defendants have induced pharmacies such as Lowitt to label containers of generic cyclandelate as "Cyclospasmol".

Plaintiff further contends that defendants are violating Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), by adopting the colors used by plaintiff and by promoting their products as comparable or equivalent, thus making "a false designation of origin" and a "false description or representation" as to the goods.

Finally plaintiff claims that by duplicating the appearance of plaintiff's capsules thus "placing an instrument of fraud" into the hands of retail pharmacists, defendants are guilty of unfair competition under New York common and statutory law.

III

This court has jurisdiction of the Lanham Act claims under 28 U.S.C. §1338(a) and, since more than $10,000 is in controversy, under 28 U.S.C. §1331(a). Those claims are sufficiently substantial to give the court jurisdiction under 28

U.S.C. §1338(b) of the related unfair competition claims. As to MD the court also has jurisdiction under 28 U.S.C. §1332, there being diversity of citizenship. MD has made a motion, now returnable September 1, 1978, to dismiss for lack of personal jurisdiction.

IV

The criteria for issuance of a preliminary injunction have been stated by the Court of Appeals for the Second Circuit: a clear showing by plaintiff of possible irreparable injury and either (1) probable success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the plaintiff. *Selchow & Righter Company v. McGraw-Hill Book Company*, 580 F. 2d 25, at p. 27 (1978).

Defendants contend that, even if these criteria are met, a preliminary injunction should not issue because of the delay in bringing the action. Plaintiff, which by the summer of 1976 knew of the existence, but perhaps not the extent and manner, of some of the defendants' sales, did not file the motion until March 20, 1978.

Certainly as to Sherry's alleged infringement of "Cyclospasmol" by using "Spasmol" laches should not bar relief. Sherry has discontinued the name, and delay in seeking to prohibit its use has caused no harm. As to the other claims it is in the interest of the litigants and the public to decide the motion on grounds addressing the merits.

For the reasons stated in this opinion the court holds that, except for the claim of trademark infringement against Sherry, plaintiff has not made the showing prerequisite to issuance of a preliminary injunction.

V

Since Sherry has discontinued the use of the name "Spasmol" the claim that it infringes "Cyclospasmol" is now of diminished significance. Sherry suggests, but does not press the point, that "Cyclospasmol" is not a valid trademark because merely descriptive of the functions of the medication. But at least in the absence of a contrary showing the court may presume a registered trademark to be valid. 15 U.S.C. §1057(b). *Maternally Yours, Inc. v. Your Maternity Shop, Inc.*, 234 F. 2d 538, 542 (2d Cir. 1956).

Sherry also claims that the discontinuation of the name makes the matter moot. In 1977 Darby acquired Sherry and with it an inventory of cyclandelate which Sherry had been selling as "Spasmol". Assertedly that inventory has now been disposed of, orders have been and are being filled with cyclandelate sold under the Rugby name, and the name Spasmol has been deleted from the new Sherry catalog.

Even assuming what is stated, plaintiff is not bound to rely on Sherry's assurances. *Consumers Union of United States, Inc. v. Admiral Corporation*, 186 F. Supp. 800, 801 (S.D.N.Y. 1960); *Mercury Record Corp. v. Buckingham Record Co.*, 226 F. Supp. 427, 429 (S.D.N.Y. 1963). Plaintiff may therefore have a preliminary injunction against Sherry's use of "Spasmol".

VI

Consideration of plaintiff's claims based on contributory infringement of the "Cyclospasmol" trademark, false description or false designation of origin of goods under Section 43(a) of the Lanham Act, and unfair competition under the New York law

requires a tracing of the process which ends with the consumption of the product.

A patient may obtain cyclandelate only on a doctor's prescription, and New York law provides the manner in which such prescription must be made. Section 6810(6) of the Education Law requires the prescription form to state conspicuously: "This prescription will be filled generically unless physician signs a line stating 'dispense as written'." Two lines must appear on the form, one over the words "substitution permissible" and the other over the words "dispense as written."[1] The physician's signature on either validates the prescription.

Unless the physician otherwise directs, the pharmacist making a substitution must indicate on the label the name and strength of the drug and its manufacturer. Where a brand name drug is dispensed, Section 6815(2)(j) requires the pharmacist, unless the prescription otherwise explicitly states, to affix the brand name and the strength of the drug.

Any pharmacist who mislabels or makes an improper substitution is by Section 6816(1) guilty of a misdemeanor and by Section 6809 subject to civil monetary penalties. In addition his license may be revoked under Section 6808.

Plaintiff sells in packages identifying itself and displaying the trademark "Cyclospasmol". When he dispenses the product

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1. Section 6816-a(1) goes further and provides that a pharmacist "shall substitute a less expensive drug" having the same active ingredients if the physician signs above the words "substitution permissible" and the drug is on a list established under the New York Health Law. Plaintiff claims that cyclandelate is not on the list, and that druggists are thus not "required" to substitute. However, they may substitute if the physician has signed on the appropriate line.

the pharmacist removes the capsules from plaintiff's packages and places them in containers bearing his own label. If he follows the law, the phramacist then includes on the label, for example, "Cyclospasmol 200mg." "Ives" need not be mentioned on the label. Defendants' cyclandelate follows a similar course. Here the pharmacist must include on the label, for example, "Cyclandelate 200mg. Premo".

Plaintiff contends that defendants, by copying the colors in which "Cyclospasmol" is sold, by not imprinting (until recently in the case of Premo) their names on the capsules, and by advising pharmacists and others that the product is the generic equivalent of "Cyclospasmol", are placing and "instrument of fraud" in the hands of pharmacists, thereby unfairly appropriating business that would otherwise go to plaintiff. Plaintiff suggests not that physicians, hospitals or pharmacists are in doubt as to the identity or source of the product but rather that dishonest pharmacists, tempted no doubt by the generally lower price of the generic drug, will, quite contrary to the explicit directions of the doctors, fill prescriptions with defendants' capsules rather than those of plaintiff. The patient, says plaintiff, seeing the customary colors (and not noticing the absence of the "Ives" imprint or supposing plaintiff to have abandoned it) will assume he is getting what the doctor ordered.

Plaintiff insists that this is no mere hypothetical scenario and points to evidence that a number of pharmacies around the country have improperly filled prescriptions for "Cyclospasmol" with generic cyclandelate. Some, like Lowitt, have gone further and have falsely labeled the containers as containing "Cyclospasmol".

According to plaintiff the only effective manner in which to halt the pharmacists' practices is to reserve exclusively to

plaintiff the blue and red colors. Then the consumer will be alerted by differences in color to any improper substitution. Plaintiff's argument presupposes that the temptation to the pharmacists is so great and their propensity to commit crimes and violate their duties, both contractual and statutory, is so widespread that nothing short of granting plaintiff a monopoly over the red and blue colors will stem their wanton and extensive disregard of physicians' orders. In short, only the chance that a consumer aroused by receiving an unaccustomed color will complain is sufficient to deter pharmacists from pursuing their unscrupulous ways.

VI

In arguing for a monopoly of the red and blue shades plaintiff merely asserts an interest implicit in any claim for trademark infringement or unfair competition. To protect a trade name or symbol is to create or extend a monopoly. *Saxlehner v. Wagner*, 216 U.S. 375, 380, 30 S. Ct. 298, 54 L. Ed. 525 (1910) (per Holmes J.); *R.C.A. Manufacturing Co. v. Whiteman*, 114 F. 2d 86 (2d Cir.), *cert. den.* 311 U.S. 712, 61 S. Ct. 393, 85 L. Ed. 463 (1940); *Eastern Wine Corporation v. Winslow-Warren, Ltd.*, 137 F. 2d 955, 957 959 (2d Cir.), *cert. den.* 320 U.S. 758, 64 S. Ct. 65, 88 L. Ed. 452 (1943). But the law recognizes and approves monopolies of many kinds, of which patents, copyrights, and trademarks or trade names or symbols are but examples. Each serves some end sufficiently desirable to overcome the interest of society in unrestricted competition. Thus the law of trademarks and unfair competition when it secures to businesses the fruits of their initiative and enterprise is thought to encourage inventiveness, *Eastern Wine Corporation v. Winslow-Warren, Ltd., supra*, at 958, and to promote orderly and honest commercial practices, *Dwinell-Wright Co. v. White House Milk Co.*, 132 F. 2d 822, 825 (2d

Cir. 1948), and perhaps even morality and gentlemanliness. *Millinery Creators' Guild, Inc. v. F.T.C.*, 109 F. 2d 175, 177 (2d Cir. 1940), *aff'd*, 312 U.S. 469, 61 S. Ct. 708, 85 L. Ed. 955 (1941); *American Safety Table Co. v. Schreiber*, 269 F. 2d 255, 272, 273 (2d Cir.), *cert. den.*, 361 U.S. 915, 80 S. Ct. 259, 4 L. Ed. 2d 185 (1959). Moreover, by preventing one seller from misleading customers into believing that the goods come from another, the courts protect customers in their choices. *Benton Announcements, Inc. v. F.T.C.*, 130 F. 2d 254, 255 (2d Cir. 1942).

In each instance the determination to allow the exclusive use of a symbol requires a balancing of the interest in encouraging such values against the effect on consumers of whatever inhibition of competition may ensue. Where the balance has not been struck by legislation, *cf.* 15 U.S.C. §1057(b) (making a certificate of registration prima facie evidence of an exclusive right to use a trademark), the process will often require a court to weigh imponderables, and much can depend on which side must bear the burden of persuasion. As to that, two Supreme Court cases involving unfair competition, *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964), and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 84 S. Ct. 779, 11 L. Ed. 2d 669 (1964), give an unmistakable sign. Both cases involved deliberate and detailed copying of previously marketed products, and the Court ruled that it was not consistent with the policy of the patent provisions in the Constitution and the patent legislation for a state to prohibit the copying of an unpatented article. If, as the Court said in the *Compco Corp.* case, the "federal policy" found in Article I, section 8, clause 8 of the Constitution (giving Congress the power to promote science by securing to inventors for "limited" times the "exclusive" right to their discoveries) and in the implementing federal statutes is to allow "free access to

copy" whatever is left by them in the public domain, 376 U.S. at 237, 84 S. Ct. 779, then the presumption must be that competition shall be the general rule and limitations on it are exceptions requiring justification. As Mr. Justice Brandeis put it in *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 122, 59 S. Ct. 109, 83 L. Ed. 73 (1938), "the consuming public is deeply interested" in the "free exercise" of the right to share in the goodwill of an article unprotected by a patent or a trademark. "[I]mitation is the life blood of competition." *American Safety Table Co. v. Schreiber, supra,* 269 F. 2d at 272. It follows that courts should be chary in granting judge-made monopolies which are both perpetual and unregulated. *Cheney Bros. v. Doris Silk Corp.*, 35 F. 2d 279, 281 (2d Cir. 1929) (per L. Hand, J.), *cert. den.*, 281 U.S. 728, 50 S. Ct. 245, 74 L. Ed. 1145 (1930).

With these principles in mind we turn to the several theories on which plaintiff seeks to obtain an injunction against defendants' practices.

VIII

Since it is the use of a "reproduction" or "copy" of a registered mark which Section 32 of the Lanham Act, 15 U.S.C. §1114, makes improper, plaintiff's claim of so-called "contributory" infringement of the trademark "Cyclospasmol" must be based on defendants' asserted inducement of the pharmacists not merely to substitute defendants' goods for plaintiff's but wrongfully to affix the "Cyclospasmol" label. No doubt the knowing and deliberate instigation of such a practice would justify holding defendants equally with the pharmacists as infringers. *Stix Products, Inc. v. United Merchants & Mfrs.*, 295 F. Supp. 479 (S.D.N.Y. 1968), is an example. There the defendant manufacturer conceived of using the infringing word in the retailers' advertising, paid for one half of their advertising

costs, and entered into hold harmless agreements with some retailers as to their use of the word. The product's assembler too was held as an infringer where it was aware of, participated in, and aided a promotional campaign to use the infringing word.

But here there is no showing that defendants have conspired with the pharmacists or counseled or suggested that they disregard the doctors' orders. As mentioned above, for a New York pharmacist to mislabel would put him at risk of criminal and civil penalties and would subject him to the loss of his license. Defendants' use of the blue and red colors, whatever its significance in assessing plaintiff's other claims, can hardly be deemed an invitation to the pharmacists to violate the penal law. A use of the same colors may make discovery of the offense less likely but it scarcely justifies holding defendants as accessories to the crime.

Before passage of the Lanham Act the doctrine of contributory trademark infringement went no further than to hold one who actively shared a retailer's infringement, as in the case, for example, of one who places the infringing label on the articles before delivering them to the retailer. *John B. Stetson Co. v. Stephen L. Stetson Co.*, 85 F. 2d 586, 588 (2d Cir.), *cert. den.* 299 U.S. 605, 57 S. Ct. 232, 81 L. Ed. 446 (1936); *Andrew Jergens Co. v. Bonded Products Corp.*, 21 F. 2d 419, 424 (2d Cir. 1927), *cert. den.* 275 U.S. 572, 48 S. Ct. 204, 72 L. Ed. 432 (1928); *Cuervo v. Jacob Henkell Co.*, 50 F. 471 (C.C.S.D.N.Y. 1892). Nothing in the language or history of Section 32 intimates that it was intended to expand the doctrine to embrace the mere copying of features not the subject of a mark.

Appendix A

IX

Plaintiff's other claim under the Lanham Act is based on Section 43(a), 15 U.S.C. §1125(a), which provides in pertinent part that anyone who affixes to or uses in connection with any goods or container for goods "a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent" the goods, and causes them to enter commerce, shall be liable to a civil action by any person who believes he is or is likely to be damaged by the false description or representation.

Defendants' alleged false descriptions and representations are said to be of two kinds. First, plaintiff contends that defendants' advertisement of its cyclandelate as "comparable" or "equivalent" to "Cyclospasmol" is false. Second, plaintiff argues that the copying of its colors is an implied representation that the product comes from plaintiff.

The former contention has not been established by plaintiff. For purposes of the motion plaintiff has conceded that the two products have the same bioavailability and are bioequivalent. One would ordinarily suppose that to recite that a drug is "comparable" or "equivalent" to that of another is to convey the impression that its effect on the consumer is comparable or equivalent. Plaintiff submits no evidence that defendants' product is unsafe or affects patients differently from "Cyclospasmol".

Plaintiff nonetheless says that defendants may not call their product comparable or equivalent because they have not received approval from the Federal Food and Drug Administration ("FDA") to market their product whereas plaintiff has. Defendants claim that the FDA has informed them

they do not need such approval. It is not clear to what extent plaintiff challenges this assertion, but, assuming the matter to be relevant at all (*see* §307 of the Food, Drug and Cosmetic Act, 21 U.S.C. §337, requiring proceedings to enforce the act to be brought in the name of the United States), at best an issue of fact would be raised as to whether defendants were required by the FDA to obtain approval.

The contention that defendants' use of the red and blue colors is a "false designation of origin" or a "false description or representation" within the meaning of Section 43(a) assumes that the colors have come to symbolize not only the product but also the producer (or at least the one who gives assurance of the product's quality.)[2] Plaintiff argues, in effect, that the colors are to be taken as representing to the patient "this will not only have the same therapeutic effect on you as Cyclospasmol, an Ives product, that you have been taking; it is in fact Ives' Cyclospasmol." Thus, says plaintiff, a use of the colors on a product equivalent to that of plaintiff but not made by it constitutes a misrepresentation though plaintiff has no patent and no trademark on the colors. It does not matter, of course, that no words articulated the alleged representation. Section 43(a) contemplates that "symbols" may falsely describe a product.

But this is not the typical "palming off" case where those who make the choice are said to be deceived. Here the patient ordinarily does not choose what drug to use or whether to buy a brand name or a generic drug. The doctors make that choice, and

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2. Since 15 U.S.C. §1060 permits an assignment of a registered mark provided the licensor supervises the licensee's use, *Dawn Donut Co. v. Hart's Food Stores, Inc.*, 267 F. 2d 358, 366, 367 (2d Cir. 1959), a trademark may not necessarily symbolize the origin of the goods.

they are under no illusion that defendants' product is that of plaintiff. Consequently the significance to the consumers of the colors is not to symbolize the source of the goods so as to enable them to discriminate between competing producers. In the prescription drug context colors serve for the consumers other purposes of which plaintiff claims one should be to alert them to unscrupulous substitutions by pharmacists. Whatever "damage" plaintiff suffers occurs because defendants use colors not likely to arouse the consumers to an illegal substitution by the pharmacist. Plaintiff therefore contends that it is a "false representation" under Section 43(a) for anyone to color their capsules like those of plaintiff, and it should be granted exclusive use of red and blue.

In determining whether or to what extent Section 43(a) accords exclusive use of colors to a business *Sears, Roebuck & Co. v. Stiffel Company, supra,* 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964); and *Compco Corp. v. Day-Brite Lighting, Inc., supra,* 376 U.S. 234, 84 S. Ct. 779, 11 L. Ed. 2d 669 (1964), must be considered. Both involved state unfair competition laws which the lower courts had used to prevent copying of unpatented designs, in one case of a "pole lamp" and in the other of a fluorescent lighting reflector. As described above, the Supreme Court held that a state's unfair competition law could not, consistently with the implication of the patent laws, prohibit copying of the designs. In the *Sears* case the court described the limitations imposed on the power of the states in the following terms:

> "Of course there could be 'confusion' as to who had manufactured these nearly identical articles. But mere inability of the public to tell two identical articles apart is not enough to support an injunction against copying or an

> award of damages for copying that which the federal patent laws permit to be copied. Doubtless a State may, in appropriate circumstances, require that goods, whether patented or unpatented, be labelled or that other precautionary steps be taken to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods. But because of the federal patent laws a State may not, when the article is unpatented and uncopyrighted, prohibit the copying of the article itself or award damages for such copying." [Footnote omitted]

376 U.S. at 232 33, 84 S. Ct. at 789.

And in the *Compco Corp.* case the Court explained further:

> "As we have said in *Sears*, while the federal patent laws prevent a State from prohibiting the copying and selling of unpatented articles, they do not stand in the way of state law, statutory or decisional, which requires those who make and sell copies to take precautions to identify their products as their own. A State of course has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original. That an article copied

> from an unpatented article could be made in some other way, that the design is 'nonfunctional' and not essential to the use of either article, that the configuration of the article copied may have a 'secondary meaning' which identifies the maker to the trade, or that there may be 'confusion' among purchasers as to which article is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling; however, and regardless of the copier's motives, neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling. *Cf. Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120, 59 S. Ct. 109, 114, 83 L. Ed. 73 (1938). And of course a State cannot hold a copier accountable in damages for failure to label or otherwise to identify his goods unless his failure is in violation of valid state statutory or decisional law requiring the copier to label or take other precautions to prevent confusion of customers as to the source of the goods." [Footnote omitted]

376 U.S. at 238-39, 84 S. Ct. at 782.

Both Supreme Court decisions dealt with the copying of physical designs, and the opinions make no mention of colors. But the means allowed to a state to prevent "palming off" were sharply restricted. Although the state could require labeling and prohibit imitation of a "marking" or "distinctive dress in the packaging of goods" so that purchasers would not be mislead as to the source, even a design's "nonfunctional" aspect which had acquired a "secondary meaning" could not be protected. It is

thus hard to believe that the Supreme Court would consider that colors, or at least those not so fancifully or ingeniously arranged as to be eligible for registration as a trademark, can constitute a "label" or "marking" so as to qualify for the exclusive use of one business. Certainly the blue and red colors used by plaintiff cannot be deemed "distinctive dress in the packaging of goods". The capsules are not part of the "packaging". They are ingested by the patient and are the "goods" themselves. The language of the *Sears* and *Compco Corp.* cases, if taken at face value, thus appears to preclude any claim that defendants engaged in "unfair competition" by using capsules colored red and blue.

These decisions addressed themselves to the federal limitations on state unfair competition laws. So far as the opinions reveal, no consideration was given to whether Section 43(a) of the Lanham Act created a federal unfair competition law as to palming off broader than that permissible to the states. However, nothing in the Act's legislative history has been cited to this court and no policy is apparent suggesting that Congress had such an intention. The reasoning of the *Sears* and *Compco Corp.* cases would thus appear to be applicable to a Section 43(a) claim.

It is suggested that the quoted language from the *Sears* and *Compco Corp.* opinions is mere dictum which should not be followed in an action for unfair competition or for violation of Section 43(a) of the Lanham Act. Indeed, the Court of Appeals for the Eighth Circuit so held in a case brought under Section 43(a). *Truck Equipment Serv. Co. v. Fruchauf Corp.*, 536 F. 2d 1210, 1214, 1215 (8th Cir.), *cert. den.*, 429 U.S. 861, 97 S. Ct. 164, 50 L. Ed. 2d 139 (1976). There the defendant decided to enter into the hopper grain trailer market and copied plaintiff's design, portions of which the court found to be "nonfunctional"

and to have acquired a "secondary meaning". Defendant also used in its sales promotion literature photographs of plaintiff's trailer. The court held that the use of the photographs constituted a "false designation of origin" within the meaning of Section 43(a). The court also appears to have held the sales of the trailers themselves to be violations of Section 43(a) because by copying the nonfunctional portion of the design defendants had misbranded their product as that of plaintiff. 536 F. 2d at 1216. The court in interpreting Section 43(a) used the old tests of "unfair competition" which the *Sears* and *Compco Corp.* opinions had deemed impermissible, namely, whether features of the product were "nonfunctional", if so whether they had acquired a "secondary meaning", and whether their use by another was likely to cause "confusion" among purchasers.

No such restrictive reading of the two Supreme Court opinions has as yet been embraced in the Second Circuit. In *Bose Corporation v. Linear Design Labs, Inc.*, 467 F. 2d 304 (2d Cir. 1972), the court had before it a loudspeaker system of a unique pentagonal shape which plaintiff deliberately marketed without affixing its name, relying on the uniqueness of the product design to establish a common law trademark showing the product's origin as plaintiff. The defendant copied the design, and plaintiff claimed this was a false representation of origin under Section 43(a). The court left open the possibility that "product appearance, in its non-functional aspects, can support a holding under §43(a) of the Lanham Act that the design functions as a[n][unregistered] trademark to indicate origin, if it has acquired a secondary meaning[.]" 467 F. 2d at 309. The court said it was unnecessary to decide whether this "purported simulation of trade dress" could give rise to a claim under Section 43(a). 467 F. 2d at 310. *Cf. Sutton Cosmetics (P.R.) v. Lander Co.*, 455 F. 2d 285 (2d Cir. 1972) (Section 43(a)

prohibits deliberate copying of a competitor's trademark and packaging design for cosmetics).

Two years later, without referring to the *Bose* case, the Second Circuit read Section 43(a) as not going so far as to require "those who purvey goods to make affirmative disclosures about those goods where necessary to prevent the deception of the purchaser." *Alfred Dunhill Limited v. Interstate Cigar Company, Inc.*, 499 F. 2d 232, 237, 238 (2d Cir. 1974). There Alfred Dunhill Limited sought to enjoin defendant from selling salvaged Dunhill brand tobacco under the Dunhill trademark without labelling it as subjected to possible water damage. The court held that there was no violation of Section 43(a), which "does not have boundless application as a remedy for unfair trade practices but is limited to false advertising as that term is generally understood." 499 F. 2d at 237.

In the light of these two opinions it is at best uncertain whether a claim may be made in this circuit under Section 43(a) based on "trade dress" or whether the Court of Appeals for the Second Circuit would agree with the Eighth Circuit in considering the quoted language of the *Sears* and *Compco Corp.* cases as not binding. It is not necessary now to decide that question or to assess the considerations which led the Supreme Court opinions to abandon as unfruitful the distinction between "functional" and "nonfunctional" aspects of a product. For even if Section 43(a) be deemed to have enacted a federal law of "unfair competition" so as to prohibit the copying of a product's "nonfunctional" features which have acquired a "secondary meaning", plaintiff is not entitled to a preliminary injunction.

First, plaintiff has not established that the colors are "nonfunctional". Assuming they have no direct physical healing value, they serve purposes other than to identify plaintiff as the

source. While we need not now consider the extent, if any, to which the use of a brand name during the life of a patent on a unique product causes that name to become generic and unprotectable when the patent expires, certainly the pale blue in which the 200 mg. capsules of Cyclospasmol were sold during the patent period may, in the case of some patients, have come to symbolize not merely the source but also the drug itself and its therapeutic effects. The drug could be obtained only from plaintiff during the term of the patent, and to the extent that the blue color represents to the consumer the chemical ingredients which offer relief it would be an extension of the patent monopoly beyond its term to grant plaintiff the perpetual and exclusive use of the unpatented color.

The blue and red shades of the 400 mg. capsules marketed first in 1975 have had a lesser time to acquire a symbolic therapeutic meaning to consumers. But here too there is no reason to suppose the colors have no function other than to identify plaintiff. Courts have never looked with favor on a demand to monopolize colors, *A. Leschen & Sons Rope Company v. Broderick & Bascom Rope Company*, 201 U.S. 166, 171, 172, 26 S. Ct. 425, 50 L. Ed. 710 (1906), and the blue and red used by plaintiff are no less functional than the pink color which the Second Circuit would not allow to be appropriated by the maker of "Pepto-Bismol". *Norwich Pharmacal Company v. Sterling Drug Co.*, 271 F. 2d 569 (2d Cir. 1959). Here, as there, it is plausible to infer that the color may present "a pleasing appearance to the customer and to the sufferer." 271 F. 2d at 572. In each case the consumer may associate the color with a beneficent effect. In any event it is fair to conclude, as defendants argue, that some patients may be fearful and offer resistance if their accustomed medication is dispensed in a different color.

Defendants argue that the colors have other functions, for example, to identify a drug in an emergency situation where an overdose is suspected. While this would plainly not be a preferred method of identification, perhaps in some situations it will be all that is immediately available, and to that extent the colors serve a practical purpose. Defendants also say that a patient may be taking several different drugs and may determine which ones to take and when by the colors. This hardly seems the most cautious way in which to take medication. But the law must recognize that individuals differ, and that to some the colors may be a signal and a protection.

Even assuming the colors to be "nonfunctional", plaintiff has not established that they have a "secondary meaning" identifying the product's source because of which consumers are moved to purchase. *Blisscraft of Hollywood v. United Plastics Co.*, 294 F.2d 694 (2d Cir. 1961).[3] Indeed, plaintiff has agreed not to rely on secondary meaning for purposes of the motion except to argue that defendants' copying in itself constitutes "evidence" of secondary meaning. No doubt copying of packaging can give rise to an inference that it has acquired a secondary meaning where no reasonable conclusion can be drawn other than that the defendant sought to pretend his goods were those of plaintiff's. *Scholl, Inc. v. Tops E.H.R. Corp.*, 185 U.S. P.Q. 754 (E.D.N.Y. 1975). But no such conclusion is

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3. Plaintiff argues that it can prevail without showing "secondary meaning" provided it can show "palming off". Doubtless where there is imitation of a trade name the use of the same colors might be "an intrinsic element" of the palming off. *Pro-phy-lac-tic Brush Co. v. Abraham & Straus*, 11 F. Supp. 660, 664 (E.D.N.Y. 1935). Where there is no copying of a trade name or the packaging but an unpatented feature of the product itself is sought to be monopolized that feature must at least have acquired a "secondary meaning". *Bose Corporation v. Linear Design, Labs, Inc., supra.*

inevitable here. Defendants could reasonably have believed that the colors represented to the patient the therapeutic properties of cyclandelate.

Finally, this is a court of equity, cautioned to be wary of granting everlasting and unsupervised monopolies. It must consider the purpose which would be served by giving one business exclusive use of blue and red and must determine whether that end can be attained by means less drastic and more suited to a competitive economy.

As mentioned, plaintiff seeks to monopolize the colors in the hope the consumers will help identify dishonest druggists. No conclusive proof has been submitted as to the extent to which this would occur, though it may be assumed that some pharmacists with fraudulent intent would be deterred if differing colors were required.

But this is not the only method of policing pharmacists. Plaintiff and the State of New York are not without resources to identify, pursue and bring to justice pharmacists who are violating their duties. In preparation for this motion plaintiff has made test purchases in New York and other states to determine whether there have been illegal substitutions. Indeed, it appears that plaintiff has knowledge of drug stores that have a proclivity toward illegal substitution. Plaintiff can bring proceedings against them, as has been done in the case of Lowitt, and can also report the violations to the state authorities for criminal prosecution, for the collection of civil monetary penalties, and for proceedings to revoke the pharmacists' licenses. Successful efforts along these lines may well have the desired general deterrent effect.

In addition, the physicians, who have been the target of plaintiff's massive promotional campaigns and who as a group are not notoriously unsympathetic to the manufacturers of brand name drugs, have it in their power to alert their patients to look for the "Ives" imprint on the capsules.

Considering all these factors the court holds that on the present papers plaintiff has not shown a violation of Section 43(a).

X

Little need be added concerning the "unfair competition" claim under New York law. The limitations imposed by the *Sears* and *Compco Corp.* opinions have already been discussed.

To the extent that New York is free to impose requirements to prevent customers from being misled as to the source of goods New York law appears to follow principles no more expansive than those adopted generally by federal and state courts. Moreover, the New York Education Law, by requiring a line on the prescription form permitting a druggist to substitute an appropriate lower priced drug, has manifested a positive policy to encourage legal substitutions and has thus added an additional consideration to the balance. For reasons already stated it is at least possible that giving plaintiff exclusive use of red and blue will inhibit legitimate substitutions which the New York legislature has found to be in the public interest.

Plaintiff has cited no authority persuasive that New York law entitles it to relief. *E.R. Squibb & Sons, Inc. v. Premo Pharmaceutical Labs, Inc.*, 195 U.S.P.Q. 545 (S.D.N.Y. 1977), although it involved a prescription drug and applied New York law, concerned the imitation of the "get-up" of the

manufacturer's packaging carton, which the pharmacist dispensed to the customer, and not a copy of the drug tablet itself. In *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762 (E.D. Mich. 1972), *aff'd* without opinion 473 F. 2d 910 (6th Cir. 1973), also a prescription drug case, the court applied the Michigan law of unfair competition, and held for the defendant, finding it had not induced pharmacists to substitute.

Merrell-National Laboratories v. Zenith Laboratories, 194 U.S.P.Q. 157 (D.N.J. 1977), appeal from injunctive order dismissed on procedural grounds, appeal from order denying motion for redetermination affirmed, 579 F.2d 786 (3rd Cir. 1978), is more directly in point. Applying New Jersey unfair competition law the court preliminarily enjoined the defendants from copying the physical appearance and colors of the plaintiff's prescription drug tablets. In that case the defendants did not submit factual affidavits opposing the preliminary injunction until they applied for "re-determination" of the motion. Only then did they set forth facts showing that the color and shape of the tablets had functional characteristics. Apparently the District Court denied redetermination in part because the belatedly offered facts had been known to the defendants when the original motion was made. The District Court opinion is therefore a dubious precedent. To the extent that its language is inconsistent with the result reached in the case at bar, this court respectfully disagrees.

Finally, plaintiff does not claim that Section 368 d of the New York General Business Law affords any broader support for its position than New York's common law of unfair competition. The Section provides in substance that likelihood of injury to business reputation or of dilution of the distinctive quality of a mark or trade name shall be ground for injunctive

relief in cases of infringement of a mark or unfair competition notwithstanding the absence of competition or confusion as to the source of the goods.

The section was apparently designed to permit injunctions in trademark, trade name and unfair competition cases where the defendant was engaged in a category of business different from that of plaintiff. *Cf. Federal Telephone & R. Corp. v. Federal Television Corp.* 180 F.2d 250, 251, 252 (2d Cir. 1950). The language has apparently never been read to expand the law of unfair competition as applied to competitors.

XI

Except for the claim of trademarks infringement against Sherry, none of plaintiff's contentions has sufficient merit to warrant issuance of a preliminary injunction. Settle order.

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 601 F. 2d 631 (2D CIR. 1979)

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 529—August Term, 1978.

(Argued May 2, 1979 Decided June 11, 1979.)

Docket No. 78-7454

IVES LABORATORIES, INC.,

Plaintiff-Appellant,

—v.—

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, LOWITT LABS ., INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants-Appellees.

Before:

FRIENDLY and MULLIGAN, *Circuit Judges,* and GAGLIARDI, *District Judge.* *

Appeal from an order of the District Court for the Eastern District of New York, Eugene H. Nickerson, *Judge,* 455 F.Supp. 939 (E.D.N.Y. 1978), denying plain-

* Judge of the United States District Court for the Southern District of New York, sitting by designation.

tiff's motion for a preliminary injunction against defendants' manufacturing and selling capsules of cyclandelate powder identical in color and size with those marketed by plaintiff under its registered trademark "Cyclospasmol." Affirmed, with instructions.

MARIE V. DRISCOLL, Esq., New York, N.Y. (Rogers, Hoge & Hills, New York, N.Y., William F. Weigel, Esq., Charles J. Raubicheck, Esq., Egon E. Berg, Esq., and Steven Baron, Esq., Of Counsel), *for Plaintiff-Appellant, Ives Laboratories, Inc.*

ROBERT V. MARROW, Esq., New York, N.Y. (Salon, Bloustein & Raybin, New York, N.Y., Leon Salon, Esq. and Lauren Friedman, Esq., Of Counsel), *for Defendants-Appellees, Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.*

SHELDON S. LUSTIGMAN, Esq., New York, N.Y. (Bass, Uliman & Lustigman, New York, N.Y.), *for Defendant-Appellee, Inwood Laboratories Incorporated.*

PETER T. COBRIN, Esq., New York, N.Y. (Kirschstein, Kirschstein, Ottinger & Cobrin, P.C., New York, N.Y., David B. Kirschstein, Esq., Of Counsel), *for Defendant-Appellee Premo Pharmaceutical Laboratories, Inc.*

Appendix B

JOHN H. SHENEFIELD, Esq., Assistant Attorney General, United States Department of Justice, Washington, D.C., Barry Grossman, Esq., Roger B. Andewelt, Esq., Robert J. Wiggers, Esq., and Andrew L. Pringle, Esq., Attorneys, Department of Justice, Of Counsel), *for the United States as Amicus Curiae.*

FRIENDLY, *Circuit Judge:*

This appeal from an order of the District Court for the Eastern District of New York denying a motion of plaintiff, Ives Laboratories, Inc., for a preliminary injunction, 455 F.Supp. 939 (1978), raises interesting questions of the application of *Sears, Roebuck & Co. v. Stiffel Company,* 376 U.S. 225 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.,* 376 U.S. 234 (1964), to the imitation of a peripheral vasodilator, dispensed only on a physician's prescription, once covered by a patent now expired and still covered by a registered trademark "Cyclospasmol". Although we find the case more difficult that did the district judge, we affirm the denial of a temporary injunction as within the discretion accorded to him.

I.

Plaintiff Ives Laboratories, Inc. (Ives) manufactures and sells Cyclospasmol to wholesalers, retail pharmacists, and hospitals. The drug, a powder whose generic name is cyclandelate, is sold in two kinds of labeled packages. One type of package is filled with pale blue capsules imprinted "Ives 4124", each containing a dosage of 200 mg. The other is filled with red-and-blue capsules imprinted "Ives

4148", each containing a dosage of 400 mg. The blue capsule had been used during the life of the patent; the blue-and-red capsule was introduced after its expiration.

Ives directs its advertising not to the consumer but to prescribing physicians and to pharmacists in hospitals and elsewhere. Until April 26, 1972, when the patent expired, the primary object of the advertising (which included the large-scale distribution of "starter" samples) was to convince the physician of the superiority of Cyclospasmol over other vasodilators; since then the advertising has had the additional objective of persuading the physician to specify Cyclospasmol rather than writing prescriptions which can be filled with competing cyclandelate preparations. The latter objective has assumed increased importance because of the enactment of "generic drug laws" by many states.[1]

Defendants Premo Pharmaceutical Laboratories, Inc. (Premo), Inwood Laboratories, Incorporated (Inwood), and MD Pharmaceutical Company, Inc. (MD), (collectively the manufacturers), purchase empty capsules which they fill with the cyclandelate powder and sell the capsules to

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1 The New York law, Education Law § 6810(6)(a), requires the prescription form to state:

> This prescription will be filled generically unless physician signs on line stating "dispense as written."

The form must contain two lines, one over the words "substitution permissible" and the other over the words "dispense as written"; the physician must sign one or the other. If the physician signs the "substitution permissible" line, substitution is mandatory if the drug is on a list established under the New York Health Law, see N.Y. Education Law § 6816-a, N.Y. Public Health Laws § 206(1)(i); in other cases substitution of the generic drug is permissible. Unless the physician otherwise directs, the pharmacist making a substitution must indicate on the label the name and strength of the drug and its manufacturer; when a brand name is dispensed, the pharmacist, unless otherwise directed by the prescription, must similarly affix on the label the brand name and strength. N.Y. Education Law § 6816-a.

wholesalers, hospitals, retail pharmacies and others. Premo and Inwood manufacture and sell both 200 mg. and 400 mg. capsules in colors essentially identical to Ives'; MD has done the same with 200 mg. capsules. Until shortly before the district court's decision, none imprinted any mark on their capsules; on June 26, 1978, Premo filed an affidavit stating that in the future it would imprint "Premo" on all its capsules. Three other defendants, Darby Drug Co., Inc. (Darby); Rugby Laboratories, Inc. (Rugby); and Sherry Pharmaceutical Co., Inc. (Sherry), (collectively "the wholesalers") purchase capsules of the sort described and resell them to other wholesalers, doctors, pharmacies and others. Both categories of defendants promote the generic product as "comparable" or "similar" or "equivalent" to Cyclospasmol; in some catalogs they refer to the color of the capsules.[2] Defendants' advertising, like plaintiff's, is directed to physicians, pharmacists, and other intermediaries, and not to the ultimate consumer. Ives conceded for the purpose of the temporary injunction motion that the cyclandelate used by defendants had the same therapeutic properties as that used in Cyclospasmol.

The complaint claimed that defendants' use of capsules having the same color or colors as those previously adopted by Ives violated its rights in three ways:

(1) as contributory infringements in violation of § 32 of the Lanham Act, 15 U.S.C. § 1114, in that the

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2 Sherry had offered the drug under the name "Spasmol" but had abandoned such use. The district court enjoined resumption of the practice, and Sherry has not appealed. Plaintiff had also named an additional defendant, Lowitt Labs Inc. (Lowitt), a retail pharmacy; the complaint charged that, on receiving a prescription for Cyclospasmol, Lowitt substituted generic cyclandelate and labeled the bottle "Cyclospasmol." The court entered a consent order prohibiting this.

similarity encouraged retail druggists to use Ives' mark "Cyclospasmol" in selling capsules not manufactured by it;

(2) as "a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent" the goods sold by defendants in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a);[3]

(3) as unfair competition under New York common and statutory law, N.Y. General Business Law § 368-d.

In a considered opinion, 455 F.Supp. 939, Judge Nickerson found that there was no sufficient evidence that defendants had been encouraging, as distinguished from merely facilitating, druggists in using Ives' mark in prescriptions filled with generic cyclandelate, and that the other claims were probably invalid, either because of the "general" law of trademarks and unfair competition or as contravening *Sears* and *Compco*. In his view, therefore, "none of plaintiff's contentions has sufficient merit to warrant issuance of a preliminary injunction." *Id.* at 952.[4]

Ives' complaint related to a wide spectrum of acts. In a state with a generic drug law like New York's these range

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3 In the trial court this claim included a contention that the product sold by defendants was not "comparable" or "equivalent" to Cyclospasmol. The judge held this claim not to have been proved, 455 F.Supp. at 946, and the contention has not been pressed on this appeal from the denial of a temporary injunction.

4 The judge referred to our formulation of the criterion for this in *Selchow & Righter Co. v. McGraw-Hill Book Company*, 580 F.2d 25, 27 (1978). Since we think it clear that Ives showed "irreparable injury" at least in the sense of impracticability of establishing the amount of damages, we must assume that the judge concluded that there was no probability of success on the merits and *either* that the questions raised by plaintiff were not sufficiently serious to make them a fair ground for litigation *or* that the balance of hardships did not tip decidedly in its favor.

from the most serious case, where the physician has specified Cyclospasmol and the druggist has filled the prescription with the generic product but has labeled it "Cyclospasmol"—admittedly actionable against the druggist—to the most innocent one, where the physician has permitted substitution and the druggist has filled the prescription with capsules of the competing manufacturer and so labeled the package. Intermediate cases are where the prescription requires Cyclospasmol and the druggist substitutes a product of the defendants naming it or not, and where the prescription permits substitution and the druggist fills it with defendant's product but names it Cyclospasmol (again clearly actionable against the druggist) or gives no name at all.[5] Similar variations can occur in other states with or without generic drug laws.

II.

It will be useful to discuss at the outset plaintiff's claim of contributory infringement in violation of § 32 of the Lanham Act, 15 U.S.C. § 1114. The judge was right in concluding that the protection conferred by that section is narrower than that afforded by § 43(a), 15 U.S.C. § 1125(a), in that the former relates only to infringement of the trademark itself and thus would apply only to cases where Ives' mark or a confusingly similar one had been used. We fear, however, that his approach to the issue may have been unduly narrow. He referred to "the knowing and deliberate instigation of such a practice", 455 F.Supp. at 945, and said that before "passage of the

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5 While many of these variations are actionable as misbranding under the New York law, see N.Y. Education Law §§ 6811(a), 6815(2)(h), 6816, these laws, aimed at protecting the consumer, do not necessarily displace the protection for competitors embodied in trademark and unfair competition law.

Lanham Act the doctrine of contributory trademark infringement went no further than to hold one who actively shared a retailer's infringement, as in the case, for example, of one who places the infringing label on the articles before delivering them to the retailer." *Id.* at 946, citing cases. While such cases would surely constitute contributory infringement, they do not mark the limits of the doctrine. The authorities later reviewed indicate to us that a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described. The proper criteria are stated in *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D. Mass. 1946) (Wyzanski, J.), affd., 162 F.2d 280 (1 Cir.), *cert. denied*, 332 U.S. 809 (1947). As will be shown below, nothing in *Sears* or *Compco* allows such practices. If the judge considered a narrower view of the doctrine of contributory infringement to be warranted because mislabeling by a New York pharmacist "would put him at risk of criminal and civil penalties and would subject him to the loss of his license" and thought that defendants would be liable for contributory infringement only if they could be held "as accessories to the crime", 455 F.Supp. at 945-46, he was in error. New York's provision of additional sanctions for confusing consumers by infringement of a trademark cannot limit the rights bestowed by federal law. However, the court was justified in concluding that Ives failed to adduce the quantum of proof necessary to require issuance of a temporary injunction for contributory infringement even on what we deem the proper standard of liability under § 32.

Ives' proof was limited to 15 instances of improper substitution and defendants conceded only that the identity of color made this easier if a druggist were so inclined.

III.

Before considering Ives' other claims, it will be useful to review what we regard as the most pertinent authorities.

We begin with two opinions of the Supreme Court. *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924), was a prescription drug case with facts close to those here.[6] Lilly had begun and continued to make and sell an unpatented prescription liquid preparation of quinine in combination with other substances, including yerba-santa and chocolate, under the name of Coco-Quinine. Predecessors of Warner later marketed a similar preparation under the name of Quin-Coco. Lilly sued for trademark infringement and unfair competition. The Court agreed with the two lower courts in dismissing the claim of trademark infringement on the ground that both names were descriptive. On the issue of unfair competition the Court held that Lilly had no right to prevent Warner from manufacturing and selling a product exactly like Coco-Quinine. That, however, was far from ending the case. The Court mentioned with disapproval that some of Warner's salesmen "suggested that, without danger of detection, prescriptions and orders for Coco-Quinine could be filled by substituting Quin-Coco" and that "[m]ore often . . . the feasibility of such a course was brought to the mind of the druggist by pointing out the identity of the two preparations and the enhanced

6 Although the opinion does not say so, the Court apparently applied its own views of trademark and unfair competition law under the principle of *Swift v. Tyson*, 41 U.S. (16 Pet.) 1 (1842).

profit to be made by selling Quin-Coco because of its lower price." 265 U.S. at 530. "That no deception was practiced on the retail dealers, and that they knew exactly what they were getting is of no consequence. The wrong was in designedly enabling the dealers to palm off the preparation as that of the respondent." *Id.* While Lilly was not entitled to the injunction granted by the court of appeals which enjoined Warner from the use of chocolate, it was entitled to "effective relief". This should include not only prohibition of acts such as those above recited but also a requirement that the packages sold the druggists "shall not only bear labels clearly distinguishing petitioner's [Warner's] bottled product from the bottled product of respondent [Lilly], but that these labels shall state affirmatively that the preparation is not to be sold or dispensed as Coco-Quinine or be used in filling prescriptions or orders calling for the latter." 265 U.S. at 532-33.

The second case, *Kellogg Company v. National Biscuit Co.*, 305 U.S. 111 (1938),[7] related to shredded wheat. The product had been originated by National's predecessor, one Perky, who had obtained a patent on the machine used in its manufacture. National marketed the product, in a pillow-shaped form, under the name of Shredded Wheat in packages picturing a dish containing two biscuits submerged in milk. Kellogg manufactured and sold a similar product under the same name, shredded wheat. After procedural complications unnecessary to detail, the Court of Appeals for the Third Circuit directed the district court to enter a decree, 96 F.2d 873 (1938), enjoining Kellogg:

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7 Mr. Justice Brandeis noted, 305 U.S. at 113 n. 1, that "[m]ost of the issues in the case involve questions of common law and hence are within the scope of *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). But no claim has been made that the local law is any different from the general law on the subject, and both parties have relied almost entirely on federal precedents."

(1) from the use of the name 'SHREDDED WHEAT' as its trade name, (2) from advertising or offering for sale its product in the form and shape of plaintiff's biscuit, and (3) from doing either.

305 U.S. at 115.

In reversing, the Supreme Court began by holding that National had no exclusive right to Shredded Wheat as a trade name both because the term was generic and because the name "as well as the product, the process and the machinery employed in making it, has been dedicated to the public" upon the expiration of Perky's patent in 1912 or shortly thereafter. Because National had allowed Shredded Wheat to become "the generic designation of the thing which has arisen during the [patent] monopoly," *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896), it would in effect extend the patent monopoly if National were to be given exclusive rights in the name.

The Court next held that National "has not the exclusive right to sell shredded wheat in the form of a pillow-shaped biscuit . . . ." This was primarily because the pillow shape was that in which shredded wheat was made under the patent. Here again Kellogg "was free to use the pillow-shaped form, subject only to the obligation to identify its product lest it be mistaken for that of the plaintiff." 305 U.S. at 120.

Finally the Court addressed itself to the question whether Kellogg was exercising its rights "fairly", i.e., "in a manner which reasonably distinguishes its product from that of plaintiff." It found that Kellogg had taken every reasonable means for doing this—using cartons distinctive in size, form and color, featuring the name Kellogg, and containing biscuits only two-thirds the size of National's. Conceding that Kellogg was sharing in the good-will of an article created by National and its predecessors, Mr.

Justice Brandeis said that "[s]haring in the goodwill of an article unprotected by patent or trademark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested." 305 U.S. at 122.

There is something for everyone in these two decisions. Defendants take comfort from so much of *Warner* as upheld that company's right to copy not only the basic ingredients of Lilly's product but their color, taste and smell; plaintiff emphasizes the severe restrictions placed on Warner in order to avoid dishonest substitution by druggists. Defendants find cheer in the holdings in *Kellogg* that National, in part because of expiration of the patent, had no rights in the name Shredded Wheat or in the pillow-shaped form. Plaintiff says that the holding as to the name was based on its generic nature; that the Court differentiated the case of a valid trademark; that the holding as to the pillow-shaped form likewise was predicated on the bases that this was what the patented machine was designed to produce and that the form was also covered by a design patent that had been held invalid and in any event had long since expired; and that, even on the premise that neither the name nor the form deserved protection, the Court still insisted on Kellogg's doing everything reasonably possible to disclose the difference in source. It argues that here in contrast, so far as the ultimate consumer is concerned, the defendants did nothing (except for Premo's recent imprinting) to disclose the difference to the consumer, although the use of other colors was entirely feasible.

We turn next to a few particularly pertinent decisions of courts of appeals in the interval between *Kellogg* and *Sears-Compco*—one before and the others after the effective date of the Lanham Act. *Smith, Kline & French*

Laboratories v. Clark & Clark, 157 F.2d 725 (3 Cir.), *cert. denied*, 329 U.S. 796 (1946), involved both patent and unfair competition claims relating to amphetamine sulphate tablets, a prescription drug. The court found that the shape, color and scoring of the tablets were functional. Partially reversing a decree perpetually enjoining Clark & Clark from manufacturing or selling these, the court held that SKF was entitled to such an injunction only during its patent monopoly and thereafter "to a decree enjoining the palming off of the defendants' product for that of SKF." This should include "[a] provision requiring the defendants to stamp their tablets with the initials C & C or some other distinguishing mark . . ." (footnote omitted), 157 F.2d at 731.[8]

Upjohn Company v. Schwartz, 246 F.2d 254 (2 Cir. 1957), also has some factual resemblance to this case. The portion of the opinion here relevant is that dealing with the prescription trade in various unpatented tablets

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8 Previous discussion in the opinion indicated that the injunction should also include a prohibition against defendant's salesmen pointing out the feasibility of substituting defendant's product for SKF's without danger of detection, 157 F.2d at 731.

Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp., 90 F.Supp. 976 (S.D.N.Y. 1950), citing *Clark & Clark*, accorded broader relief. The case related to two prescription drugs, Benzedrine (amphetamine sulphate) and Dexedrine (dextroamphetamine sulphate). Plaintiff decided to market these in a new and distinctive heart shape, colored orange for Dexedrine and brown for Benzedrine. Defendant sent postcards to druggists offering to sell the generic drugs in tablets which were exact replicas of plaintiff's; imprinted on the pictorial representations of the tablets was the notation "Color Guaranteed". A later mailing added the words "orange" and "tan". Finding that the shape and color were non-functional and that SKF's advertising had endowed them with secondary meaning, the court entered a temporary injunction restraining defendant from marketing the generic drugs "in tablets having the combination of shape and colors of plaintiff's products or in any other shape and colors so closely resembling the combination of shape and colors of plaintiff's products as to be likely to enable druggists to palm off defendants' products as plaintiff's products."

marketed by Upjohn under differing trade names. There was evidence that two of defendant's salesmen had distributed cards, apparently quite similar to the catalogs in this case, containing a list of defendant's products with a space alongside each on which the names of similar products manufactured by Upjohn had been filled in and had suggested substitution. This court held that such action constituted unfair competition in violation of New York law even though Upjohn had not established secondary meaning and there was no proof of actual substitution. We directed, 246 F.2d at 262, that defendant:

> should be enjoined from either directly or indirectly, representing or suggesting to any one selling any pharmaceutical products similar in contents and appearance to plaintiff's products that such similar products may be substituted for the products of the plaintiff when the latter are prescribed or requested by a physician; and that on the sale of any such products he be required to attach to bottles or containers of a size not made for direct over-the-counter sale, a notice that the contents are not to be sold or dispensed as the product of the plaintiff.

Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569 (2 Cir. 1959), *cert. denied*, 362 U.S. 919 (1960), although heavily relied on by defendants for its statement "[t]hat a color may become someone's exclusive property as a perpetual monopoly in connection with a specific product has been rejected by the courts throughout the years", 271 F.2d at 572, is not of so much assistance to them as they claim. The case dealt with preparations sold in the manufacturers' bottles over-the-counter. The court held that where defendant's product differed in name, container shape and label, copying of the pink color of

plaintiff's liquid was not unfair competition in the absence of proof of secondary meaning or "such practices as constitute palming off, actual deception or appropriation of another's property." 271 F.2d at 571. The court cited *Upjohn Co. v. Schwartz, supra,* as an instance of palming off. *Id.*

This brings us to *Sears* and *Compco, supra,* 376 U.S. 225 and 234. Their precise holding was that a state may not confer protection under its law of unfair competition against the retail sale of articles which were copied from others manufactured under invalid design patents (in *Sears* also under an invalid mechanical patent), simply because of confusion or likelihood of confusion.[9] There is no indication that either Stiffel's lamps or Day-Brite's reflectors were trademarked, although the lamps bore Stiffel tags and the fixtures of which the reflectors were a part were identified by a catalog number. The Sears lamps were sold at retail without identifying tags (although the cartons containing them were marked) and there was some evidence of actual confusion, 376 U.S. at 226-27. On the other hand the Court found "considerable evidence of the care taken by Compco to prevent customer confusion, including clearly labeling both the fixtures and the containers in which they were shipped and not selling through manufacturers' representatives who handled competing lines." 376 U.S. at 237. The holdings clearly apply to goods covered by an expired patent with the same force (or arguably even more, see Brown, Product Simulation, 64 Colum. L. Rev. 1216, 1218-19 (1964)), as to an invalid patent.

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9 In *Compco,* 376 U.S. at 238, the Court accepted the somewhat dubious finding of the trial court "that the configuration of Day- Brite's fixture identified Day-Brite to the trade because the arrangement of the ribbing had, like a trademark, acquired a 'secondary meaning' by which that particular design was associated with Day-Brite."

It has been said that if the lower courts in *Sears* and *Compco* had rested their decisions on "general" principles of unfair competition law rather than on the law of Illinois, the Supreme Court would not have needed more than a citation of *Kellogg* to justify reversal. Brown, Product Simulation, *supra*, at 1216. It was this probably unwarranted reliance, see 376 U.S. at 227 n. 2, that led the Court to take a constitutional ground—preemption by federal patent law—and then to explain how far the preemption extended. The explanation was made in two passages that have been subjected to minute scrutiny:

> Sears has been held liable here for unfair competition because of a finding of likelihood of confusion based only on the fact that Sears' lamp was copied from Stiffel's unpatented lamp and that consequently the two looked exactly alike. Of course there could be "confusion" as to who had manufactured these nearly identical articles. But mere inability of the public to tell two identical articles apart is not enough to support an injunction against copying or an award of damages for copying that which the federal patent laws permit to be copied. Doubtless a State may, in appropriate circumstances, require that goods, whether patented or unpatented, be labeled or that other precautionary steps be taken to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods.[9] But because of the federal patent laws a State may not, when the article is un-

patented and uncopyrighted, prohibit the copying of the article itself or award damages for such copying.

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9 It seems apparent that Illinois has not seen fit to impose liability on sellers who do not label their goods. Neither the discussions in the opinions below nor the briefs before us cite any Illinois statute or decision requiring labeling.

Sears, 376 U.S. at 232-33.

> As we have said in *Sears*, while the federal patent laws prevent a State from prohibiting the copying and selling of unpatented articles, they do not stand in the way of state law, statutory or decisional, which requires those who make and sell copies to take precautions to identify their products as their own. A State of course has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original. That an article copied from an unpatented article could be made in some other way, that the design is "nonfunctional" and not essential to the use of either article, that the configuration of the article copied may have a "secondary meaning" which identifies the maker to the trade, or that there may be "confusion" among purchasers as to which article is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling; however, and regardless of the copier's motives, neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling.

Compco, 376 U.S. at 238.

Some, including dissenting Justices, have thought the basic principles of *Sears* and *Compco* were undermined by *Goldstein v. California*, 412 U.S. 546 (1973) (sustaining California law affording state copyright protection for

subject not eligible under the applicable federal copyright law), and *Kewanee Oil Corp. v. Bicron Corp.*, 416 U.S. 470 (1974) (sustaining validity of state trade secret common law). See, e.g., Dannay, The Sears-Compco Doctrine Today; Trademarks and Unfair Competition, 67 Trademark Rep. 132 (1977); The Supreme Court, 1972 Term, 87 Harv. L. Rev. 1, 282 (1973); Zammet, The Ghost of Sears-Compco is Finally Laid to Rest (Or Is It?), 3 Hofstra L. Rev. 37 (1975). However, the majority in both cases disclaimed any intention to depart from *Sears* and *Compco*.

Only a few cases have dealt with the effect of *Sears* and *Compco* on simulation of the color of a trademarked drug. *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F.Supp. 762, 769-70 (E.D. Mich. 1972), aff'd without opinion, 473 F.2d 910 (6 Cir. 1973), assumed that the protection afforded by *Smith, Kline & French Laboratories v. Clark & Clark, supra*, 157 F.2d 725, and *Upjohn Co. v. Schwartz*, 246 F.2d 254, had survived *Sears* and *Compco* but denied relief for inadequacy of proof of either actual or suggested substitution or secondary meaning. In *Merrell-National Laboratories, Inc., v. Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977), on facts quite similar to those here, the court issued a preliminary injunction against manufacturers because of "the mere fact that they sold and distributed to the defendant pharmacies and instrumentality of trade which could be passed off as plaintiff's products." Although the Third Circuit affirmed, 579 F.2d 786 (1978), it noted that only after the district court's decision had the manufacturer submitted factual affidavits challenging plaintiff's allegations of unlawful substitution, claiming that these were authorized under New Jersey's generic drug law, and attempting to show a functional basis for the copying; the affirmance was explicitly limited to a holding that the

denial of a motion to redetermine the preliminary injunction on the basis of this new, and contradicted, material was not an abuse of discretion.[10] Quite recently the decision here under review was followed in *Boehringer Ingelheim G. m. b. H. v. Premo Pharmaceutical Laboratories, Inc.*, D.N.J., No. 79-738, decided March 15, 1979, where there was no proof of secondary meaning or illegal substitution.

IV.

Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)[11] goes beyond § 32 in making certain types of unfair competition federal statutory torts, whether or not they involve infringement of a registered trademark. *L'Aiglon Apparel, Inc. v. Lana Lobell, Inc.*, 214 F.2d 649 (3 Cir. 1954); *Federal-Mogul-Bower Bearings, Inc. v. Azoff*, 313 F.2d 405 (6 Cir. 1963). On the other hand, as was said in

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10 Judge Garth, concurring, said that if all the factual material were properly before the court of appeals, he "would have strenuously urged a different disposition on the merits as to the 'palming off' issue" on the basis of *Sears* and *Compco*, 579 F.2d at 792.

11 This reads:

> (a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

an early case under the statute, § 43(a) "should be construed to include only such false descriptions or representations as are of substantially the same economic nature as those which involve infringement or other improper use of trade-marks. It should not be interpreted so as to bring within its scope any kind of undesirable business practice which involves deception, when such practices are outside the field of the trade-mark laws." *Samson Crane Co. v. Union National Sales, Inc.*, 87 F.Supp. 218, 222 (D. Mass. 1949), aff'd per curiam, 180 F.2d 896 (1 Cir. 1950). In this circuit Judge Herlands said much the same in an opinion subsequent to *Sears* and *Compco*, *Geisel v. Poynter Products, Inc.*, 283 F.Supp. 261, 266-68 (S.D.N.Y. 1968). Ives' claim is that, under the circumstances of this case the distinctive color of its capsules is entitled to protection under § 43(a) and that *Sears* and *Compco* were not intended to limit rights accorded by another federal statute.

It is surely true that in the *Sears* and *Compco* opinions the Supreme Court said nothing about the federal tort created by § 43(a).[12] Stiffel's and Day-Brite's claims were treated as resting solely on state unfair competition law which was held invalid as in conflict with federal patent law. The opinions can be read as limited to rights claimed under state unfair competition law granting protection equivalent to that of the federal patent or copyright laws for products not enjoying valid patent or copyright protection. The Court, it can be strongly argued, had no need to be concerned with marking out the boundaries of

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12 This was natural since neither Stiffel nor Day-Brite made any claim under § 43(a). The Lanham Act was cited to the Supreme Court only by the Government's *amicus* brief in a *cf.* type of reference to the refusal to grant trademark registration to functional configurations in *Application of Diester Concentrator Co.*, 289 F.2d 496 (CCPA 1961).

a federal tort over which it had complete control and which Congress could contract if the courts were pressing it further than that body desired.[13] The Eighth Circuit took essentially this position in *Truck Equipment Service Co. v. Fruehauf Corp.*, 536 F.2d 1210, 1214-15, *cert. denied*, 429 U.S. 861 (1976). The court there sustained a claim under § 43(a) for copying the exterior design of a hopper grain trailer which was found to be nonfunctional and to have acquired a secondary meaning.[14] While we previously left this question open in *Bose Corp. v. Linear Design Labs, Inc.*, 467 F.2d 304, 309-10 (1972), we are now prepared to agree with the Eighth Circuit.

Assuming that the law developed by federal courts under § 43(a) prior to *Sears* and *Compco* continues to govern and that the precise strictures there addressed to

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13 A contrary argument could be constructed on the basis that Art. I, § 8, authorizes Congress to secure "to authors and inventors the exclusive right to their respective writings and discoveries" only "for limited times." See Bender, Product Simulation, 64 Colum. L. Rev. 1228, 1230 (1964). However, nothing in the *Sears* and *Compco* opinions suggests that the Court was aiming shafts at Congress, and it would be hard to argue that the time limitation on the power of Congress to protect "writings and discoveries" limits its power under the commerce clause to protect trademarks or other symbols of origin. A commentator has categorically declared that "*Sears-Compco* do not affect rights under other federal statutes." Dannay, The Sears-Compco Doctrine Today: Trademarks and Unfair Competition, 67 Trademark Reporter 132, 143 (1977).

14 After quoting the passage from *Compco* which we have quoted above, the court characterized the Supreme Court's language as dictum, 536 F.2d at 1214. We would say rather that it did not purport to be addressed to rights recognized by § 43(a) of the Lanham Act.

It is of interest that, as noted in Comment, Product Simulation in the Eighth Circuit, 57 Neb. L. Rev. 91 (1978), the trial court eventually decided that, because of the extensive sales by Fruehauf, the shape was not identified with plaintiff as source, and modified the injunction merely to prohibit the deceptive advertising and to require labeling.

the states may not be applicable to a claim under that section, this still leaves the question whether Ives showed a probability of success or a fair ground for litigation and a balance of hardships tipping decidedly in its favor. A good statement of the law under § 43(a) is in *Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9 Cir. 1952), quoted in *Bliss v. Gotham Industries, Inc.*, 316 F.2d 848, 855 (9 Cir. 1963), on which the Eighth Circuit relied in the *Truck Equipment* case:

> Imitation of the physical details and designs of a competitor's product may be actionable, if the particular features imitated are 'non-functional' and have acquired a secondary meaning. Crescent Tool Co. v. Kilborn & Bishop Co., 2 Cir., 1917, 247 F. 299. But, where the features are 'functional' there is normally no right to relief. 'Functional' in this sense might be said to connote other than a trade-mark purpose. If the particular feature is an important ingredient in the commercial success of the product, the interest in free competition permits its imitation in the absence of a patent or copyright. On the other hand, where the feature or, more aptly, design, is a mere arbitrary embellishment, a form of dress for the goods primarily adopted for purposes of identification and individuality and, hence, unrelated to basic consumer demands in connection with the product, imitation may be forbidden where the requisite showing of secondary meaning is made. Under such circumstances, since effective competition may be undertaken without imitation, the law grants protection.

One would not initially suppose the color of a capsule to be functional. Unlike the chocolate in the *Warner* case, *supra*, the blue and blue-and-red coatings of Ives' capsules

do not contribute to their efficacy; any other colors would do as well.[15] The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors, cf. *Morrissey v. Proctor & Gamble Co.*, 379 F.2d 675 (1 Cir. 1967), does not seem persuasive; the evidence showed that, in addition to the other primary colors, an endless number of color combinations was available to the defendants. The case for functionality thus depends on the evidence proffered by defendants that copying whatever colors Ives had chosen served a number of utilitarian purposes, see 455 F.Supp. at 949-50, essential to effective competition. At this stage of the case we need not go beyond saying that the judge was warranted in considering this to be fairly arguable.

With respect to secondary meaning we cannot say that Ives would necessarily be unable to establish that consumers had come to associate the blue and blue-and-red colors with the trademark Cyclospasmol. Mr. Justice Holmes said long ago, *American Waltham Watch Co. v. United States Watch Co.*, 173 Mass. 85, 87 (1899):

> It is true that a man cannot appropriate a geographical name, but neither can he a color, or any part of the English language, or even a proper name to the exclusion of others whose names are like his. Yet a color in connection with a sufficiently complex combination of other things may be recognized as saying so circumstantially that the defendant's goods are the plaintiff's as to pass the injunction line.

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15 While color was held to be functional in *Smith, Kline & French Labs v. Clark & Clark, supra*, 157 F.2d at 730, this was because white was the natural color of the tablets and there would be some extra cost in coating them. Here the defendants must place the powder in a capsule and one color is no more expensive than another.

It is significant that, given the method of sale, Ives had no way of identifying Cyclospasmol to the ultimate consumer other than by the color of the capsule and by the imprint on it, which is contended to be of dubious value. See Note, Unfair Competition and the Doctrine of Functionality, 64 Colum. L. Rev. 544, 557-58 and nn. 93 & 94 (1964). This distinguishes the case from *Norwich Pharmacal Co. v. Sterling Drug, Inc., supra,* 271 F.2d 569, where differences in name, labelling and packaging seen by the consumer were such that the court thought "it stretches credulity to imagine a purchaser confusing these disparate articles." 271 F.2d at 571. Also the fact that the association was due to Ives' having been the exclusive source of cyclandelate during the patent period does not deprive Ives of an opportunity to show that a non-functional configuration or trade dress had developed secondary meaning, see, e.g., *Mine Safety Appliances Co. v. Electric Storage Battery Co.,* 405 F.2d 901, 902 n. 2 (CCPA 1969); *Application of Mogen David Wine Corp.,* 328 F.2d 925 (CCPA 1964) and 372 F.2d 539 (CCPA 1967), and we see no basis in principle for saying that simply because the colored capsule is ingested, the color cannot constitute "trade dress". However, plaintiff "agreed not to rely on secondary meaning for purposes of the motion except to argue that defendants' copying in itself constitutes 'evidence' of secondary meaning," 455 F.Supp at 950.

We find rather less merit in plaintiff's claims under New York law than in those under § 43(a) of the Lanham Act. It is true that we have recognized the breadth of the relief which New York affords against unfair competition, *Flexitized Inc. v. National Flexitized Corp.,* 335 F.2d 774, 781-82 (1964), *cert. denied* 380 U.S. 913 (1965), and there took a rather limited view of the extent to which

the then recent *Sears* decision had interfered with this, 335 F.2d at 781 n. 4. Apart from the question whether the *Flexitized* footnote adequately recognized the blow dealt by *Sears* and *Compco* to state unfair competition laws, "New York law" now includes its generic drug law, Education Law §§ 6810-6826, and we do not know how New York will strike the balance between unfair competition claims of manufacturers of branded drugs and the policy of generic drug laws facilitating substitution when the physician has authorized this. On this aspect of the case, defendants' claims that patients would be put off in accepting substitution by a change from the familiar colors, if factually established, see Swenson, Property Rights in the Color and Shapes of Capsules, 32 Food Drug & Cosm. L. J. 361, 367-68 (1977),[16] would be especially pertinent. Whether plaintiff would be entitled to relief under the unfair competition law of other states, particularly those without generic drug laws, is not before us.

The upshot of our consideration is that while we are not so convinced that *Sears* and *Compco* are an insurmountable barrier to plaintiff as was the district judge and, indeed, believe them to have only tangential bearing on the Lanham Act claims, this is an appropriate case for applying the "rule" that denial of a temporary injunction should not be reversed save for "abuse" of discretion. *State of New York v. Nuclear Regulatory Commission*, 550 F.2d 745, 750-53 (2 Cir. 1977) and cases there cited. Although some depositions were taken, the motion was heard largely on affidavits. As noted above, the evidence of improper substitution was limited to 15 prescriptions.[17]

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16 Mr. Swenson is trademark counsel to Eli Lilly & Co.

17 In 12 instances the product was labeled as Cyclospasmol.

Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices. Although plaintiff doubtless made the required minimal showing of "irreparable injury", namely, that if it is entitled to a final injunction, its interim damages cannot be calculated with sufficient accuracy to make damages an adequate substitute, see *Buffalo Courier-Express Inc. v. Buffalo Evening News, Inc.*, No. 77-7617, decided April 16, 1979, slip opinions 2183, 2203-04 (2 Cir.), there is no showing that its business will be seriously imperiled in the interval before a decision can be rendered after a trial; on the other hand, the issuance of a preliminary injunction would clearly have wreaked serious harm on the defendants. In sum, we cannot say that Ives sufficiently demonstrated probability of success for the broad injunction that it demanded and, while it did tender issues affording a fair ground for litigation, the balance of hardships did not tip decidedly in its favor, see note 4, *supra*.

The order is therefore affirmed. After trial the district court will, of course, consider whether even if under our analysis Ives is not entitled to the full relief demanded, it should not be awarded more limited relief of the sort granted in *Warner, Kellogg* and other cases.

APPENDIX C — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 488 F. SUPP. 394 (E.D.N.Y. 1980)

United States District Court
E.D. New York

No. 78 C 372

April 15, 1980

IVES LABORATORIES, INC.,

Plaintiff,

v.

DARBY DRUG CO., INC., Inwood Laboratories Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Laboratories Co., Inc.,

Defendants.

First drug manufacturer brought action against drug wholesalers and other manufacturers for alleged contributory infringement and false designation of origin in violation of Lanham Act, as well as violation of New York Unfair Competition Law, in connection with marketing of cyclandelate. The United States District Court for the Eastern District of New York, Eugene H. Nickerson, J., 455 F. Supp. 939, entered order denying motion for preliminary injunction, and appeal was taken. The Court of Appeals, 601 F.2d 631, affirmed. Following trial to court, the District Court, Nickerson, J., held that: (1) evidence established that defendants did not suggest, even by implication, that pharmacists fill bottles with generic drug

cyclandelate and apply first manufacturer's trademark, "Cyclospasmol," and evidence did not establish that defendants continued to sell the generic drug to pharmacists whom defendants knew or had reason to know were engaging in such practice, and thus evidence failed to establish contributory infringement, and (2) evidence established that use by all manufacturers and wholesalers of blue and blue and red colors for pills was functional, and first manufacturer failed to establish that such colors indicated sponsorship or origin, and thus first manufacturer failed to establish that the colors had acquired secondary meaning so as to justify it having monopoly over use of such colors.

Complaint dismissed except for judgment permanently enjoining party from using word "Spasmol" in marketing the drug.

* * *

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Bass, Ullman & Lustigman, New York City (Steven R. Trost, New York City, of counsel), for defendant Inwood.

Appendix C

MEMORANDUM AND ORDER

NICKERSON, District Judge.

Plaintiff Ives Laboratories, Inc. ("Ives"), which makes and sells the prescription drug cyclandelate under the registered trademark Cyclospasmol, brought this action seeking an injunction against defendants, manufacturers or wholesalers of generic cyclandelate. Ives claims violations of the Trademark Act of 1946, as amended, (the "Lanham Act"), 15 U.S.C. §§1051ff., and of New York statutory and common law. The court has jurisdiction pursuant to 28 U.S.C. §§1331 and 1338.

On Ives' motion for a preliminary injunction this court temporarily enjoined defendant Sherry Pharmaceutical Co., Inc. ("Sherry") from using the name Spasmol, but otherwise denied Ives temporary relief, 455 F. Supp. 939 (D.C.N.Y. 1978), and the Court of Appeals affirmed, 601 F.2d 631 (2d Cir. 1979). The case was then tried to the court. Familiarity with the prior opinions is assumed.

I

The drug cyclandelate, a white powder, is a peripheral vasodilator claimed to produce an increase in blood flow and thereby inhibit the progressive conditions caused by certain vascular diseases which tend to occur in the aged. Cyclandelate is therefore prescribed for a long period of time, generally for the rest of the patient's life. For some years Ives, its predecessors and its parent company American Home Products Corporation have sold the drug under the mark Cyclospasmol, and until the patent on cyclandelate expired in April 26, 1972, had the exclusive right to make and sell the drug in the United States.

Ives has been marketing 200 mg. dosages in a pale blue capsule imprinted "Ives 4124" since 1962, and 400 mg. dosages in a red and blue capsule imprinted "Ives 4148" since 1975.

Because the drug may be dispensed only on prescription, Ives has directed its considerable advertising and promotion not to the general public but primarily to physicians. Some two hundred and thirty so-called "detail" men have made personal visits to doctors distributing numerous samples and various promotional materials. Advertising and promotional expenses have been in excess of $10,000,000. Ives' sales of the drug since 1962 have exceeded $106,000,000.

Of the defendants remaining in the case three are manufacturers, namely, Premo Pharmaceutical Laboratories, Inc. ("Premo"), Inwood Laboratories, Incorporated ("Inwood"), and MD Pharmaceutical Company, Inc. ("MD") (collectively "the manufacturers"). All three purchase cyclandelate powder and empty capsules and assemble the product for sale to wholesalers and hospitals. Inwood and MD also sell to retail pharmacies. Premo and Inwood sell 200 mg. and 400 mg. capsules in colors identical to those used by Ives. MD does the same with 200 mg. capsules. Since the action was brought, Premo has imprinted the word Premo on its capsules and Inwood has imprinted "NDC 258" on its capsules. MD sells capsules bearing no imprint. Defendants Darby Drug Co., Inc. ("Darby"), Rugby Laboratories, Inc. ("Rugby"), and Sherry (collectively "the wholesalers") purchase capsules of the kind made by the manufacturers and sell them primarily to physicians and pharmacies.

All the defendants promote the generic product as "comparable" or "similar" or "equivalent" to Cyclospasmol, and

in some catalogs refer to the color of the capsules. Defendants' cyclandelate contains the same active ingredient as Cyclospasmol, and Ives offered no proof at the trial that defendants' product had a therapeutic effect different from that of Cyclospasmol.

Sherry had offered the drug under the name Spasmol, but abandoned that name prior to the motion for a preliminary injunction. The remaining defendants do not sell under a brand name.

Ives sells to druggists and wholesalers in packages identifying its name and displaying the trademark Cyclospasmol. Pharmacists then dispense the capsules in smaller bottles with their own labels. In New York State the New York Drug Substitution Law spells out the pharmacist's duty. Section 6810(6) of the Education Law requires the prescription form to recite that it will be filled generically unless the doctor signs over the line stating "dispense as written". The other line which must appear on the form reads "substitution permissible". If the doctor signs over that line, Section 6816-a(i) requires the druggist to "substitute a less expensive drug" having the same active ingredients provided it appears on a list established under the New York Health Law. If the drug is not on the list, as cyclandelate is not, the druggist may but need not substitute the less expensive drug.

Unless the physician otherwise directs, the pharmacist must include on the label the strength of the drug and its brand name, if it has one, or, if it is sold under the generic name, that name and the name of the manufacturer. Thus, for example, if dispensing a 200 mg. dosage of Ives' product the pharmacist should state on the label, "Cyclospasmol 200 mg.", or, if dispensing Premo's product, "Cyclandelate 200 mg. Premo".

Appendix C

Ives' chief objective in this action is to prohibit defendants from marketing cyclandelate in capsules of the same blue and blue and red colors as Ives uses.

II

There is no reason why the temporary injunction against Sherry prohibiting use of the name "Spasmol" should not be made permanent.

III

Ives' claim that defendants are guilty of contributory infringement under Section 32 of the Lanham Act, 15 U.S.C. §1114, was not proven. The court finds that defendants did not suggest, even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark Cyclospasmol. Nor did Ives show that defendants continued to sell the generic drug to pharmacists who defendants knew or had reason to know were engaging in such a practice. 601 F.2d at 636.

Defendants do not "detail" their products by making personal visits to pharmacists, and defendants' names appear on their packages of cyclandelate capsules. Therefore any suggestion by defendants that pharmacists mislabel must be found in defendants' catalogs and promotional materials. These materials cannot fairly be read as suggesting to druggists that they affix Ives' mark to bottles containing defendants' capsules.

Moreover, such incidents of mislabeling as were proven were not shown to have been induced by defendants. There was no proof of illegal substitution accompanied by mislabeling beyond the few instances referred to on the motion for a

preliminary injunction. Ives did offer evidence at trial of a few instances of legal substitution where the word Cyclospasmol was improperly used on the label. Some Ives test shoppers gave a prescription for Cyclospasmol signed on the line over "substitution permissible" to forty-two pharmacists in New York selected from a list supplied by Ives and forty-one from a list of drug stores in Hayes Directory. Of the forty-two on the Ives list twenty-four dispensed Cyclospasmol, and eighteen dispensed the generic product. Six of those eighteen included the word Cyclospasmol on the label. Of the forty-one on the Hayes Directory list twenty-four dispensed Cyclospasmol and seventeen dispensed the generic product. Four of those seventeen included the word Cyclospasmol on the label.

Of the total of ten pharmacists who dispensed generic cyclandelate and also used the word Cyclospasmol on the label, four used the term "generic Cyclospasmol" or "Cyclospasmol generic" and one the term "Cyclospasmol Gen." Nine of the ten informed the person buying the capsules that the generic product had been dispensed. Only one appears to have charged a higher "brand" price. This evidence hardly justifies an inference that defendants' catalogs impliedly invited druggists to mislabel.

To the extent the druggists who were test shopped by Ives mislabeled they appear not deliberately to have been attempting to pass off the generic product as Cyclospasmol but rather to have misunderstood the precise requirements of the New York Drug Substitution Law. Indeed, the misunderstanding of the law is confirmed by the numerous instances in which pharmacists dispensed Cyclospasmol and, although a generic substitution was permitted by the prescription, erroneously stated to the person presenting the prescription that New York law prohibited them from filling it with a generic product.

Appendix C

In accordance with the direction of the Court of Appeals this court has considered whether Ives should have limited relief of the sort mentioned in *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526, 532-33, 44 S. Ct. 615, 618, 68 L. Ed. 1161 (1924). The Court has concluded that it would not be useful to require defendants to recite on their packages that the product is not to be dispensed as Cyclospasmol. Defendants' packages do not represent that they contain Cyclospasmol, and the evidence shows that druggists are well aware of the difference between the brand and the generic product. As noted above, any mislabeling stemmed from doubt as to the requirements of the generic drug law, not from inducement by defendants. Statements on defendants' packages are hardly likely to deter those isolated instances of deliberate and fraudulent substitution by pharmacists. Perhaps recourse to the civil and criminal penalties available will do so.

Nor would it be fruitful to require all defendants to print their names on the capsules. The evidence showed that the capsules are so small that such an imprint would be of little if any value.

The court holds that plaintiff is not entitled to relief against defendants for contributory infringement of the trademark Cyclospasmol.

IV

Ives' chief claim is that defendants are violating Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a). That section provides, in pertinent part, that one who uses in connection with goods "a false designation of origin, or any false description or representation, including words or other symbols tending falsely

to describe or represent" the goods shall be liable in a civil action to "any person who believes that he is or is likely to be damaged by the use of any such false description or representation."

Ives contends first that it was "false" for defendants to promote their product as "comparable" or "equivalent" to Cyclospasmol. This claim was not proven. Indeed, Ives offered no evidence on the point and admitted that defendants' product has the same active ingredient as Cyclospasmol.

Ives' most serious contention is that defendants' use of the blue and blue and red colors is "a false designation of origin" or a "false description or representation" of defendants' product and that Ives should therefore have the exclusive use of those colors in selling cyclandelate. This court must follow the Court of Appeals' holding, 601 F.2d at 639-42, as to *Sears, Roebuck & Co. v. Stiffel Company*, 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 84 S. Ct. 779, 11 L. Ed. 2d 669 (1964), and accordingly considers whether or not the colors are "functional" and, if they are not, whether they have acquired a "secondary meaning" so as to justify Ives having a monopoly over them.

The Court of Appeals quoted, 601 F. 2d at 642-43, as a "good statement of the law" an excerpt from *Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952). That quotation recites that the word "functional" connotes other than a trademark purpose and that "[i]f the particular feature is an important ingredient in the commercial success of the product, the interest in free competition permits its imitation in the absence of a patent or copyright."

Appendix C

The court finds that the colors are functional in several respects. First, many elderly patients associate the appearance of their medication with its therapeutic effect. There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors. Other patients eventually accept equivalent drugs of a different appearance if their physician assures them that the prescription was filled correctly but are caused considerable anxiety and confusion by the change. When patients associate the drug with its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage. Thus color is an important ingredient in the commercial success of the product.

Second, some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. One doctor testified that he prepared a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs. While this practice is not universal, clearly some doctors use the appearance of a drug in communicating with their patients and in assisting them to take the correct medications at the appropriate times.

Third, to some limited extent color is also useful to doctors and hospital emergency rooms in identifying overdoses of drugs. There was testimony that the color of a capsule provides one clue in an often difficult and hurried effort to determine what a patient has ingested.

The functional aspect of the color of the capsules is further evidenced by the fact that the parent of Inwood discontinued sale of cyclandelate in a green capsule because the different color was not accepted by hospitals, pharmacies and wholesalers in

the light of the potential for confusion. One hospital official testified that he refused to purchase cyclandelate in a green capsule.

A different situation would be presented if wholesalers, pharmacies and hospitals insisted on purchasing generic cyclandelate in colors identical to those of Ives so that they could unlawfully pass off the generic product as that of Ives. But nothing in the record suggests such a motive. The fact is that, not surprisingly, the colors have come to represent to large numbers of those taking cyclandelate not its source but its ingredients and their effects. The colors are thus functional to the patients as well as to doctors and hospitals.

But even if the colors are not functional in the sense intended by the Court of Appeals, Ives failed to show that the colors indicate sponsorship or origin and have therefore acquired a secondary meaning.

To establish secondary meaning a plaintiff "must show that the primary significance of the term in the minds of the consuming public is not the product but the producer." *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 118, 59 S. Ct. 109, 113, 83 L. Ed. 73 (1938). As the Court of Appeals indicated, 601 F. 2d at 643, in quoting from *Waltham Watch Co. v. United States Watch Co.*, 173 Mass. 85, 87, 53 N.E. 141, 142 (1899) (Holmes, J.), "a color in connection with a sufficiently complex combination of other things may be recognized as saying so circumstantially that the defendant's goods are the plaintiff's as to pass the injunctive line." *See also Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd.*, 604 F.2d 200, 203-204 (2d Cir. 1979). But the colors must "say" that "the defendant's goods are the plaintiff's," in other words, must convey the message not merely that the goods have the same

active ingredients and effect but that they are in fact the plaintiff's goods. In short, in order to establish secondary meaning Ives must demonstrate that patients suppose that the blue and blue and red colors indicate the source, albeit the anonymous source, of the drug and not its chemical ingredients or its function.

Doctors are, of course, well aware that generic and brand name drugs come from different sources. Ives did not contend that in deciding on a prescription doctors were confused by the identical colors. Rather Ives sought to establish that the colors had a secondary meaning to the patient.

Ives failed to do this. The doctors who testified believed that patients do not associate the appearance of a drug capsule with the manufacturer or other source but with the drug's effect on the patient's disability. Patients tend to identify capsule colors with their ailments, for example, "my red heart pill". Ives made no showing that any patient took the colors to mean that the drug came from a particular source.

Ives offered testimony as to a survey said to be relevant to secondary meaning. Those taking the survey refused to reveal the identity of the actual interviewers or those interviewed. There was thus no way in which the defendants could test the trustworthiness of the results. For this reason the court would in any event accord the survey very little weight. But even assuming that the survey's techniques were sound (as to which the court does not express an opinion), the survey did not constitute proof that the colors had acquired a secondary meaning.

Thirty-six patients who were taking the blue or blue and red Cyclospasmol capsules were interviewed. Of the thirty-six, one third were not even aware that Cyclospasmol had been

prescribed for them. Of the other twenty-four, only twelve spontaneously identified the blue or blue and red generic capsules as Cyclospasmol. The remaining twelve who did not at first say the capsules were then given a card listing ten names of drugs including Cyclospasmol (but not cyclandelate), and finally identified the capsules as Cyclospasmol.

The court finds significant not how many patients named Cyclospasmol but how few did. All of them had been prescribed the Cyclospasmol brand. All of them took only that brand. The survey did not indicate that any of them had ever heard any other name for the drug. Yet only twelve people, a third of the entire sample, could without prompting associate the word Cyclospasmol with capsules of colors identical to those of Ives. Moreover, as to those twelve there was no evidence that they supposed that Cyclospasmol was a brand name or indicated the source of the drug.

Ives argues that because "Cyclospasmol" is a trademark which only it can use, a patient who identifies a cyclandelate capsule as "Cyclospasmol" is necessarily indicating that he believes the drug comes from a single source. But even as to the trademark itself we must "remember that relief always depends upon the idea that no man shall be allowed to mislead people into supposing that his goods are the plaintiff's, and that there can be no right or remedy until plaintiff can show that at least presumptively this will result." *Bayer Co. v. United Drug Co.*, 272 F. 505, 509-510 (S.D.N.Y. 1921) (L. Hand, J.).

No doubt to physicians and pharmacists the word "Cyclospasmol" signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaigns, and they play no role in choosing what drug to buy. Nothing in the record suggests that they

"understand by the word anything more than a kind of drug to which for one reason or another they [have] become habituated." *Id.* at 510. Such patients as read their prescriptions do not attribute to Cyclospasmol "any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue." *Id.*

Thus, one cannot infer from the fact that patients recognize the name Cyclospasmol that they appreciate that the drug they receive comes from a single source. If they do not know that the word designates a single source, it follows that a color they associate with the name does not signify to them a single source and cannot acquire a secondary meaning.

No doubt one can imagine circumstances under which a patient believes the word Cyclospasmol to be a brand name and therefore associates the colors with one source. For example, a doctor or druggist might explain to the patient that Cyclospasmol is one brand of cyclandelate. For that patient the blue and blue and red colors may perhaps attain a secondary meaning. But Ives did not offer proof that any patient received some such explanation from a physician or a pharmacist. More importantly, no question in the survey was designed to show whether patients supposed that Cyclospasmol emanated from a single, although unidentified, source.

Ives claims that the interest of patients in receiving the very drug prescribed by their doctor will not be adequately protected unless Ives has a monopoly over the colors. Implicit in this argument is the contention that even if Ives cannot show secondary meaning it is entitled to exclusive use of its capsule colors because there is no other way to identify its product to its ultimate consumers. However, the Lanham Act does not purport to confer "property rights", but, as noted, only to prohibit a

"false description or representation" of a product. Since Ives did not show that the blue and blue and red capsule colors had acquired a secondary meaning, there was no "false description or representation".

For this reason, the fact that defendants intentionally duplicated the blue and blue and red colors does not prove the existence of secondary meaning. Unless the colors bespeak the source of the capsules, defendants have every right to imitate them. As Justice Brandeis said in *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 122, 59 S. Ct. 109, 115, 83 L. Ed. 73 (1938), "Sharing in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested."

Ives' failure of proof highlights the difficulty of proving secondary meaning to consumers in the prescription drug market. In urging that Section 43(a) of the Lanham Act be read to grant Ives a perpetual monopoly over the blue and blue and red colors, Ives cites cases involving both prescription drugs and ordinary goods sold over the counter. But decisions concerning goods which the seller promotes directly to the consumer cannot indiscriminately be used as authority in a case concerning prescription drugs. Where the advertising and promotion are aimed at the customers who make the choice of which product to buy, they may indeed take a non-functional feature to indicate not merely the product but also the producer. In that case, vast expenditures for advertising may suggest that the advertising was successful in implanting in the minds of the consumer the idea that certain features by which the product is promoted identify its source. But extensive promotion to physicians does not establish that they have passed along to their patients any message as to source. For that reason secondary

meaning will perhaps be difficult to establish in those prescription drug cases where the patient never sees the manufacturer's packaging. Here Ives certainly did not establish secondary meaning.

The court concludes that Ives has not made out a violation of Section 43(a) of the Lanham Act.

V

Little need be added to the discussion in the prior opinions of Ives' claims under New York law. *See* 455 F. Supp. at 951; 601 F. 2d at 644. Ives contends primarily that whether or not the blue and blue and red colors have acquired a secondary meaning and thus constitute a false representation, the New York law of unfair competition should be construed to protect patients by making it easy for them to detect instances in which the pharmacist has made an improper substitution of the generic for the brand name drug.

Assuming that this contention is not foreclosed by *Sears, Roebuck & Co. v. Stiffel Company*, 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 87 S. Ct. 779, 11 L. Ed. 2d 669 (1964), this interest of the patients must be weighed against the policy expressed in the New York Education Law to encourage legal substitution of lower priced drugs. One of Ives' witnesses testified that improper substitution is rare, and Ives showed only a few instances of it. This infrequency may be explained in part by the fact that illegal substitution is subject to both civil and criminal penalties under New York law. To require different capsule colors might to some small extent deter a wrongdoer but it would also severely inhibit legal substitution which the legislature deems to be in the public interest. When the

competitive injury which as injunction would cause to defendants is added to the balance, the patients' ease in detecting a potential improper substitution is outweighed by the interest in fostering the use of generic substitutes.

VI

The foregoing constitutes the court's findings of fact and conclusions of law. Plaintiff may have judgment permanently enjoining Sherry from using the word "Spasmol". Otherwise the complaint is dismissed. So ordered.

APPENDIX D — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 638 F. 2d 538 (2D CIR. 1981)

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 150—September Term, 1980

(Argued September 5, 1980 Decided January 8, 1981)

Docket No. 80-7314

IVES LABORATORIES, INC.,

Plaintiff-Appellant,

—against—

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants-Appellees.

Before:

LUMBARD, MANSFIELD and MULLIGAN,

Circuit Judges.

Appendix D

Appeal from a judgment of the District Court for the Eastern District of New York entered by Judge Eugene H. Nickerson, after a non-jury trial, dismissing plaintiff's suit against defendants for violation of §§ 32 and 43(a) of the Lanham Act, 15 U.S.C. §§ 1114 and 1125(a), and New York State unfair competition laws.

Reversed and remanded.

MARIE V. DRISCOLL, Esq., New York, NY (David C. Stimson, Esq., Egon E. Berg, Esq., Steven Baron, Esq., Rogers Hoge & Hills, New York, NY, of counsel), *for Appellant.*

PETER T. COBRIN, Esq., New York, NY (Martin W. Schiffmiller, Esq., Kirschstein, Kirschstein, Ottinger & Cobrin, New York, NY, of counsel), *for Appellee Premo Pharmaceutical Laboratories, Inc.*

STEVEN R. TROST, Esq., New York, NY (Bass, Ullman & Lustigman, New York, NY, of counsel), *for Appellee Inwood Laboratories Incorporated.*

ROBERT V. MARROW, Esq., New York, NY (Salon, Marrow & Dyckman, New York, NY, of counsel), *for Appellees Darby Drug Co, MD Pharmaceutical Company, Inc., and Sherry Pharmaceutical Co., Inc.*

Appendix D

MANSFIELD, *Circuit Judge*:

Ives Laboratories, Inc. ("Ives") brought suit in the District Court for the Eastern District of New York against appellees, who are drug manufacturers and wholesalers, claiming that their manufacture and distribution of a generic drug using capsules identical in color, shape, and size to those long used by Ives in its equivalent trademarked product violated §§ 32 and 43(a) of the Lanham Act, 15 U.S.C. §§ 1114 and 1125(a), and New York State unfair competition laws.[1] The district court,

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1 Title 15 U.S.C. § 1114 reads as follows:

"§ 1114. *Remedies; infringement; innocent infringement by printers and publishers*

(1) Any person who shall, without the consent of the registrant—

(a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or

(b) reproduce, counterfeit, copy, or colorably imitate a registered mark and apply such reproduction, counterfeit, copy, or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive,

shall be liable in a civil action by the registrant for the remedies hereinafter provided. Under subsection (b) of this section, the registrant shall not be entitled to recover profits or damages unless the acts have been committed with knowledge that such imitation is intended to be used to cause confusion, or to cause mistake, or to deceive.

(2) Notwithstanding any other provision of this chapter, the remedies given to the owner of the right infringed shall be limited as follows: (a) Where an infringer is engaged solely in the business of printing the mark for others and establishes that he was an innocent infringer the owner of the right infringed shall be entitled as against such infringer only to an injunction against future printing; (b) where the infringement complained of is contained in or is part of paid advertising matter in a newspaper, magazine, or other similar

Nickerson, J., denied Ives' motion for a preliminary injunction, 455 F. Supp. 939. Upon appeal we affirmed, noting that "we find the case more difficult than did the district judge." 601 F.2d 631, 634. On remand the district court, after a bench trial, found for the appellees.[2] 488 F. Supp. 394. We reverse on the ground that the undisputed

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periodical the remedies of the owner of the right infringed as against the publisher or distributor of such newspaper, magazine, or other similar periodical shall be confined to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar periodical: *Provided*, That these limitations shall apply only to innocent infringers; (c) injunction relief shall not be available to the owner of the right infringed in respect of an issue of a newspaper, magazine, or other similar periodical containing infringing matter when restraining the dissemination of such infringing matter in any particular issue of such periodical would delay the delivery of such issue after the regular time therefor, and such delay would be due to the method by which publication and distribution of such periodical is customarily conducted in accordance with sound business practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction or restraining order with respect to such infringing matter."

Title 15 U.S.C. § 1125(a) provides:

"§ 1125. *False designations of origin and false descriptions forbidden*

"(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any false description or representation."

2 The only part of plaintiff's complaint which the district court did not dismiss after trial was Ives' request for a judgment permanently enjoining defendant Sherry Pharmaceutical Co., Inc., from using the word "Spasmol" in marketing cyclandelate.

evidence establishes a violation of § 32 and remand for further proceedings not inconsistent with this opinion.[3] In view of our holding in favor of Ives on the § 32 issue we express no views on the other issues raised by it on this appeal.

Ives has for some years manufactured a prescription drug called CYCLOSPASMOL. CYCLOSPASMOL is a peripheral vasodilator designed to produce an increase in blood flow; it is most commonly prescribed for ingestion by elderly patients who are experiencing progressive circulatory difficulties. Until 1972 Ives held a patent on CYCLOSPASMOL. Since that time it has continued to hold a trademark to the name CYCLOSPASMOL, but several generic drug manufacturers (including some of the appellees) have begun selling bioequivalents of CYCLOSPASMOL under the generic name "cyclandelate."

Ever since it began manufacturing CYCLOSPASMOL, Ives has used distinctive, colorful gelatin capsules as containers for the CYCLOSPASMOL powder. The 200 mg. capsule is pale blue; the 400 mg. capsule is red and blue. When appellees Premo Pharmaceutical Laboratories, Inc. ("Premo"), Inwood Laboratories, Incorporated ("Inwood"), and MD Pharmaceutical Company, Inc. ("MD") (collectively "the defendant manufacturers") began marketing cyclandelate, they intentionally chose to use gelatin capsules which were identical in color, shape, and size to those used by Ives even though scores of other colors, color combinations, and sizes were available.[4]

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3 Plaintiff seeks a wide range of remedies, including an injunction, the destruction of certain drug products and promotional materials, and damages. On remand, the district court will need to examine these issues in light of the remedy provisions of the Lanham Act, §§ 32-39, 15 U.S.C. §§ 1114-21.

4 Initially the capsules used by the defendant manufacturers bore no imprint of any kind, whereas the Ives' capsules were marked "Ives

Because CYCLOSPASMOL may only be dispensed by prescription, Ives has directed its CYCLOSPASMOL promotional efforts toward physicians, not patients. Some 230 "detail" men make periodic visits to physicians' offices on Ives' behalf, distributing samples and promotional material. Ives also places advertisements for CYCLOSPASMOL in professional journals read by physicians. The defendant manufacturers, on the other hand, have no similar network of detail men, and do not advertise routinely in professional magazines. They instead make their sales primarily through catalogs, which are distributed widely in the wholesale industry. Some of the catalogs contain charts which pair each generic product being offered with the name brand product for which it may be substituted and offer the generic product at a substantially lower price. The defendant wholesalers (Darby Drug Co., Inc. ("Darby"), Rugby Laboratories, Inc. ("Rugby"), and Sherry Pharmaceutical Co., Inc. ("Sherry")) purchase generic cyclandelate in capsules identical in appearance to those made by the defendant manufacturers and sell them at wholesale, primarily to physicians and pharmacies, at lower prices than those charged by Ives for its trademarked CYCLOSPASMOL.

Ives contends that appellees violated § 32 of the Lanham Act because their deliberate use of look-alike capsules and pro-substitution catalogs encouraged retail druggists to substitute generic cyclandelate illegally for CYCLOSPASMOL. In his first opinion, which denied

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4124" (200 mg.) and "Ives 4148" (400 mg.) in small letters. After this action was brought, Premo began placing the word "Premo" in small print on its capsules and Inwood likewise began labeling its capsules with the insignia "NDC 258" in small letters. In all other respects the CYCLOSPASMOL capsules sold by Ives and the cyclandelate capsules sold by defendants are identical.

plaintiff's motion for a preliminary injunction, Judge Nickerson reasoned that Ives' § 32 claim would only be viable if it could show "that defendants have conspired with the pharmacists or counseled or suggested that they disregard the doctors' orders."[5] 455 F. Supp. at 945. Finding that no such showing had been made, he rejected Ives' § 32 argument.

On appeal from this denial of preliminary relief we recognized that, although a classic case of retailer infringement occurs where a druggist illegally substitutes a generic drug for CYCLOSPASMOL prescribed by the doctor, a violation of § 32 for infringement also arises in the "intermediate" case when "the prescription permits substitution and the druggist fills it with defendant's [generic] product but names it Cyclospasmol." 601 F.2d at

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5 In New York State the pharmacist's freedom to fill brand name prescriptions with generic substitutes is circumscribed by statute. Prescription forms used by doctors bear two signature lines: one labeled "Dispense as Written," and one labeled "Substitution Permissible." N.Y. Educ. Law § 6810(6). If the physician signs over the line indicating "Dispense as Written," the pharmacist must follow his instructions exactly. If, on the other hand, the doctor signs over the line indicating "Substitution Permissible," the pharmacist must fill the prescription with the generic equivalent if the drug prescribed appears on a list prepared by the state. *Id.* at § 6816-a(1); N.Y. Pub. Health Law § 206(1)(o). If substitution is allowed by the physician but the prescribed drug does not appear on the state list (and CYCLOSPASMOL currently does not), the pharmacist is free to substitute or not as he wishes.

Unless the physician otherwise directs, pharmacists filling prescriptions with a generic drug must indicate on the prescription label the name of the manufacturer as well as the generic name of the drug, N.Y. Educ. Law § 6816-a(1)(c); on the other hand, if a trademarked drug such as CYCLOSPASMOL is involved, no indication of manufacturer is required on the label. Thus, a prescription for 200 mg. capsules of CYCLOSPASMOL, which has been signed by the physician over the "Substitution Permissible" line, may be filled in one of only two ways: (1) with CYCLOSPASMOL, in which case the pill bottle should bear a label reading CYCLOSPASMOL 200 mg."; or (2) with a generic cyclandelate such as that manufactured by Premo, in which case the label should read "Cyclandelate 200 mg. Premo."

636. We went on to question whether the district court's reading of § 32 had been too rigid:

> "We fear . . . that his [Judge Nickerson's] approach to the issue may have been unduly narrow. He referred to 'the knowing and deliberate instigation of such a practice' . . . and said that before 'passage of the Lanham Act the doctrine of contributory trademark infringement went no further than to hold one who actively shared a retailer's infringement, as in the case, for example, of one who places the infringing label on the articles before delivering them to the retailer.' . . . While such cases would surely constitute contributory infringement, they do not mark the limits of the doctrine. The authorities later reviewed indicate to us that *a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label,* or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described." 601 F.2d at 636 (emphasis supplied).

However, Judge Friendly concluded that on the record then before the court

> "the court was justified in concluding that Ives failed to adduce the quantum of proof necessary to require issuance of a temporary injunction for contributory infringement even on what we deem the proper standard of liability under § 32. Ives' proof was limited to 15 instances of improper substitution and defendants conceded only that the identity of color made this easier if a druggist were so inclined." *Id.*

On remand the district court heard Ives' evidence on the § 32 claim, and concluded that the factual showing necessary to prove plaintiff's case had once again not been made:

> "The court finds that defendants did not suggest, even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark Cyclospasmol. Nor did Ives show that defendants continued to sell the generic drug to pharmacists who defendants knew or had reason to know were engaging in such a practice." 488 F. Supp. at 397.

According to the district court, the new evidence introduced at trial on this point was limited to the following instances of mislabeling:

> "Some Ives test shoppers gave a prescription for Cyclospasmol signed on the line over 'substitution permissible' to forty-two pharmacists in New York selected from a list supplied by Ives and forty-one from a list of drug stores in Hayes Directory. Of the forty-two on the Ives list twenty-four dispensed Cyclospasmol, and eighteen dispensed the generic product. Six of those eighteen included the word Cyclospasmol on the label. Of the forty-one on the Hayes Directory list twenty-four dispensed Cyclospasmol and seventeen dispensed the generic product. Four of those seventeen included the word Cyclospasmol on the label.
>
> "Of the total of ten pharmacists who dispensed generic cyclandelate and also used the word Cyclospasmol on the label, four used the term 'generic Cyclospasmol' or 'Cyclospasmol generic' and one

> the term 'Cyclospasmol Gen.' Nine of the ten informed the person buying the capsules that the generic product had been dispensed.[*] Only one appears to have charged a higher 'brand' price. This evidence hardly justifies an inference that defendants' catalogs impliedly invited druggists to mislabel." *Id.*

In the district court's opinion, this frequent mislabeling of cyclandelate as CYCLOSPASMOL was occurring not because appellees had suggested that pharmacists do so, but rather because pharmacists "misunderstood the precise requirements of the New York Drug Substitution Law." *Id.* "[A]ny mislabeling stemmed from doubt as to the requirements of the generic drug law, not from inducement by defendants." *Id.* at 398.

DISCUSSION

Since the governing legal principles have already been set forth in Judge Friendly's opinion upon the earlier appeal, 601 F.2d 631 (2d Cir. 1979), we need not repeat them here. Applying those principles, we believe that the district court, in considering Ives' § 32 claim, erred upon remand in declining to give any weight to additional evidence offered by Ives indicating that appellees' use of identically-colored, look-alike drug capsules assisted druggists in labeling generic cyclandelate as Ives' trademarked product CYCLOSPASMOL, and that they could

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[6] This does not, however, mean that pharmacists as a rule spontaneously inform their customers whenever a generic substitution is made. The shoppers conducting the survey were instructed to inquire after receiving the filled prescription whether the generic substitute was in stock. Not surprisingly, a number of pharmacists responded by merely pointing to the generic with which the shopper's prescription had just been filled.

reasonably anticipate that the use of these capsules would have such an effect.

At the preliminary injunction hearing Ives introduced evidence of some 15 instances of illegal substitution by druggists of the generic drug cyclandelate for CYCLOSPASMOL after the latter had been prescribed, which we found insufficient to warrant reversal of the district court's denial of preliminary injunctive relief even though, taking into consideration the normal reluctance of any druggist to admit illegal conduct, it was surprising that Ives was able to produce as many such instances as it did. Recognizing this deficiency, Ives at trial introduced substantial additional evidence of "intermediate cases" of contributory infringement in which a druggist who was authorized to substitute the generic drug cyclandelate improperly used Ives' trademark CYCLOSPASMOL on the label.

In preparation for trial Ives carried out in a rigorous, impartial manner two series of drug shoppings at pharmacies. In each, the prescription reading "CYCLOSPASMOL—Substitution Permissible" was used. The first series consisted of having the prescriptions filled at 42 pharmacies from a list of drug stores believed to carry both CYCLOSPASMOL and cyclandelate. The second involved the submission of the same prescription to 41 pharmacies selected at random from the Hayes Directory of Pharmacies in New York State. The shoppings revealed that in 29% of the cases pharmacists mislabeled the generic product in some form (6 out of 18 pharmacists in the first shopping and 4 out of 17 in the second shopping).[7] In addition Ives adduced evidence that in 9 out of

[7] In his dissent Judge Mulligan asserts that the percentage figure should be 12% or "10 out of the entire sample of 83" rather than 29%. We disagree. The prescription used in the test was for CYCLOSPAS-

17 instances where patients retained bottles of prescribed generic cyclandelate the bottles had been mislabeled with the trademark name CYCLOSPASMOL in some form.

This pattern of illegal substitution and mislabeling in New York is precisely the sort of showing which we held would be probative of plaintiff's § 32 claim, stating that "a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label." 601 F.2d at 636.

The additional evidence introduced by Ives at trial was clearly sufficient to establish a § 32 violation. By using capsules of identical color, size and shape, together with a catalog describing their appearance and listing comparative prices of CYCLOSPASMOL and generic cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage. This amounted to a

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MOL—Substitution Permissible." The objective of the study was to determine how many of the druggists who substituted the generic drug for CYCLOSPASMOL mislabeled the drug as CYCLOSPASMOL. Where a prescription was filled by the druggist with CYCLOSPASMOL itself, there obviously was no substitution and therefore no occasion to mislabel. Of the 35 instances where druggists substituted the generic drug there were 10 cases, or approximately 29%, in which the generic drug was mislabeled as CYCLOSPASMOL.

Premo also conducted a shopping survey of 50 pharmacies in preparation for trial, the results of which were introduced by stipulation. However, its survey was designed to refute allegations of illegal substitution rather than of improper labeling. The prescription used by Premo did not read "Substitution Permissible" but instead consisted of 25 prescriptions for CYCLOSPASMOL to be dispensed as written and 25 for cyclandelate to be dispensed as written. Nevertheless, 2 of the cyclandelate prescriptions were filled with bottles labeled "CYCLOSPASMOL."

suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct. By using look-alike capsules, appellees also reduced the likelihood that patients who were given a generic substitute would bring that fact to their doctor's (or their druggist's) attention. Similar activity has been enjoined as enabling druggists to defraud by palming off, *Upjohn Co. v. Schwartz,* 246 F.2d 254 (2d Cir. 1957); *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc.,* 194 U.S.P.Q. 157, 159-60 (D.N.J. 1977); *E.R. Squibb & Sons, Inc. v. Premo Pharmaceutical Labs, Inc.,* 195 U.S.P.Q. 545 (S.D.N.Y. 1977); *Smith Kline & French Laboratories v. Broder,* 125 U.S.P.Q. 299 (S.D. Tex. 1959). We think appellees' activity should be enjoined as well.

The second premise of the district court's decision, that mislabeling occurs because of confusion rather than as a result of appellees' inducement, finds no support in the record. Indeed, it was the district court itself, in a short and casual exchange with a witness, which suggested that the mislabeling might result from pharmacists' thinking that CYCLOSPASMOL was a generic name rather than a trademark. The witness to whom he made the suggestion responded ambiguously, agreeing only that some pharmacists "may not be knowledgeable concerning the intricacies of the law." No evidence in the form of witnesses or surveys supporting the district court's suggestion was ever introduced at trial.

Against the absence of concrete evidence in the record supporting the district court's explanation for mislabeling we are now in possession of additional undisputed evidence, which we may judicially notice, suggesting that illegal substitution and mislabeling in New York are neither *de minimis* nor inadvertent. During the month of

Appendix D

May, 1980, six indictments were handed down in the New York City area alleging illegal substitution and mislabeling of generic cyclandelate in prescriptions requiring CYCLOSPASMOL.[8] These indictments, which reflect the grand jurors' views that reasonable grounds exist for charging the druggists with engagement in such illegal activities, is inconsistent with appellees' contention that mislabeling is rare or unintentional.

Appellees have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically-colored, look-alike cyclandelate capsules instead of capsules of a different color, size or shape, which would minimize the practice of mislabeling, illegal substitution or confusion. Their arguments that look-alike capsules reduce patient confusion or anxiety in taking medication, enable doctors to communicate with

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8 The indictments in Bronx County are: *People v. Melrose Pharmacy, Inc.* (No. 1056-80); *People v. James Detura* (No. 1057-80); *People v. B & B Pharmacy, Inc.* (No. 1061-80); and *People v. Benjamin Bernstein* (No. 1062-80). The indictments in Kings County are: *People v. Pueblos Pharmacy, Inc.* (No. 1235-80); and *People v. Soel Melero* (No. 1236-80).

It is clear that under Rule 201 of the Federal Rules of Evidence judicial notice may be taken during an appeal. While it is somewhat unusual to take judicial notice of proceedings not directly involving the parties to an action, we believe that notice can properly be taken here where the facts being noticed are not in dispute, *In re Phillips*, 593 F.2d 356, 358 (8th Cir. 1979), the indictments themselves are part of the public record of a court, *Happy Investment Group v. Lakeworld Properties, Inc.*, 396 F. Supp. 175, 183 n.6 (N.D. Cal. 1975), and the appeal being heard is not from a criminal conviction, cf. *United States v. Fatico*, 458 F. Supp. 388, 395 (E.D.N.Y. 1978) (sentencing). See generally *United States v. Gonzalez*, 442 F.2d 698, 707 & n.4 (2d Cir. 1971); *United Keans of America v. McGovern*, 453 F. Supp. 836, 838-39 (N.D. Ala. 1978); *Insurance Co. of North America v. National Steel Service Center, Inc.*, 391 F. Supp. 512, 518 (N.D. W. Va. 1975).

In taking judicial notice of these indictments, we of course express no opinion as to the guilt or innocence of those indicted. We merely take judicial notice of the fact that several grand juries have examined evidence of illegal substitution and mislabeling and have found it sufficient to warrant indictment.

patients more easily concerning their medication, and aid in their identification of the drug in an emergency situation, are unconvincing. Although a few doctors and one pharmacist were of the view that patients receiving capsules in a size, shape or color different from the medication they usually receive may at first believe that they have the wrong drug, there was no evidence of any instances of such confusion, much less that it was widespread, or that it could not easily be cured by explaining the change to the patient, either voluntarily in accordance with accepted professional practice or in response to the patient's inquiry. Indeed one witness called by appellees (Lawler) testified that when the doctor or druggist explains that the different color or different shaped capsules are the same generic drug, patients do not refuse to accept and use it. There was no evidence that doctors or druggists refused to furnish such explanations. No patient testified to confusion or anxiety. Nor did appellees offer any survey of patients' attitudes with respect to the matter. On the contrary, there was evidence that many generic drugs (e.g., cyclandelate made by W. E. Hauck and so-called "branded" generics) are successfully marketed in capsules or tablets that do not copy Ives' trademarked product. Thus the inference is inescapable that appellees' use of identically-colored, shaped and sized capsules was in anticipation that they would successfully capitalize upon public acceptance of CYCLOSPASMOL by reason of the fact that at least a substantial number of druggists would either substitute the generic product illegally or mislabel it as CYCLOSPASMOL.

Finally, we note that the current use of look-alike capsules makes detection of mislabeling very unlikely. The doctors who write prescriptions for CYCLOSPASMOL rarely see the capsules which their patients end up receiv-

ing at the pharmacy. The patients who have those prescriptions filled will normally be lulled by the look-alike cyclandelate capsules into thinking that they are receiving what their doctor prescribed.

The simplest way to reduce illegal substitution and mislabeling is to require that cyclandelate be sold in capsules which do not resemble those used for CYCLOSPASMOL. This would alert the patient to the possibility that he has been given cyclandelate when his doctor specifically prescribed CYCLOSPASMOL, as well as put him on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received. Such a change could be made by appellees without any appreciable difficulty or expense. It would also give Ives the protection to which it is entitled for its trademarked product.

The judgment of the district court is reversed and the case remanded for further proceedings consistent with the foregoing.

MULLIGAN, *Circuit Judge* (dissenting):

I would affirm on the opinion of Judge Nickerson on all of the issues presented on this appeal.[1] The majority

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1 The principal contention of Ives has been that the defendants violated section 43(a) of the Lanham Act. That issue has not been addressed by the majority. Suffice it to say that Ives' position that the generic drug supplied by the defendants was falsely described as comparable to or equivalent to Cyclospasmol was not supported on trial by any evidence and was abandoned on appeal. The contention that the use of identically colored capsules was a false designation of origin since the Ives' capsules had acquired a secondary meaning and that the color was not functional within *Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1943) was also found by the trial court to be without merit. While not reaching the § 43(a) violation the majority does disregard the finding of functionality.

here reverses solely on the ground that "undisputed evidence establishes a violation of § 32 of the Lanham Act." I respectfully disagree.

I have no dispute with the interpretation of § 32 of the Lanham Act which the majority purports to apply. Indeed it was set forth by Judge Friendly for a panel of this court of which I was a member, in Ives I, 601 F.2d 631 (1979). There is and can be no claim that Judge Nickerson misunderstood the law announced in our prior opinion.

With respect to the claimed § 32 Lanham Act violation, we found in Ives I, *supra,* that Ives had failed to adduce sufficient evidence of contributory infringement. "[T]he evidence of improper substitution was limited to 15 prescriptions. Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Id.* at 644. (The parties stipulated on trial that there were only 13 instances of such practices.)

Our inquiry then must focus upon whatever additional evidence was adduced by Ives on the trial. Ives submitted the results of some 83 test shoppings. Forty-two of these shoppings were conducted at pharmacies selected from a list prepared by Ives. One of Ives' own witnesses conceded that the selection of druggists by Ives' detail men for this list might have been tainted by knowledge of this litigation. While Ives would object to the characterization of these pharmacies as "bad actors," it would seem apparent that this list might be suspect and within the class of pharmacies to which we referred in our prior opinion. There is admittedly not a scintilla of evidence to suggest that the defendants sold to those pharmacies knowing or having reason to believe that illegal substitution or mislabeling had occurred. I therefore would con-

clude that under our prior opinion, the further evidence gleaned from such shoppings would hardly be probative of any violation by the defendants of Section 32. In any event the statement by the majority that Ives carried out in an "impartial manner" two series of drug shoppings is not entirely accurate.

Forty-one shoppings were impartially selected from a list contained in Hayes Druggist Directory, 1979 ed. Even taking the results of both series of shoppings, however, the results confirm Judge Nickerson's finding that there was no reasonable inference of an invitation by the defendants to mislabel. The testing hardly supports a finding that the practices condemned were "much more widespread" than those disclosed when this case first came to us in Ives I.

Only 10 out of the entire sample of 83 mislabeled the generic drug as Cyclospasmol. This amounts to some 12% of the sample and not the 29% estimated by the majority. More significantly, five of these ten included the word generic or its abbreviation before or after the word Cyclospasmol. Nine of the ten druggists advised the patient that they were dispensing the generic drug. Only one druggist out of 83 attempted an illegal substitution, charged a "higher" brand price and thus reaped any profit from a color confusion. These facts support rather than discredit the finding of the District Court that druggists were confused with respect to the labeling requirements of the new generic drug law and were not motivated by profit considerations. Any pharmacist who intended to mislabel would simply place the name Cyclospasmol on the label and charge a higher price. He would hardly put generic on the label and inform the customer that he was receiving a generic. In sum, the additional

evidence adds nothing of substance to the record previously before this court.[2]

It is also significant that the defendants did not employ "detail" men who contacted druggists and thus were in a position to encourage substitution or mislabeling.[3] This fact completely distinguishes this case from *Upjohn Co. v. Schwartz*, 246 F.2d 254 (2d Cir. 1957) which is relied upon in the majority opinion. That case involved the use of look alike products but there was also proof that the defendant's salesmen had contacted druggists for the very purpose of encouraging substitution. No such evidence exists here.

The sampling by Ives of druggists on the Sec. 32 issue was in any event inadequate. On the secondary meaning question (§ 43(a)) which involved a survey of doctors, a list of some 12,000 physicians was assembled and a random selection of names was made in twenty randomly selected geographical areas throughout the country. On the Section 32 contributory infringement issue, however, only 83 druggists located in the State of New York and only half randomly selected, were questioned. There are some 3,000 pharmacists in the State of New York alone. The record indicates that Cyclospasmol is prescribed to some 100,000 patients nationwide. A testing of some 83 druggists in one state does not present a sufficient basis after our remand for the injunctive relief sought here particularly in light of the results obtained.

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2 An Ives witness, the President of the New York State Pharmaceutical Society, testified that he knew personally of no illegal substitution of generic for brand name drugs, and in answer to a question from the court stated that he did not believe the practice was widespread.

3 Ives, on the other hand, employs detail men who personally visit pharmacists and admittedly know which of them have a proclivity for illegal substitution.

Appendix D

In an effort to bolster what I believe is a weak record, the majority takes judicial notice of the fact that subsequent to the trial in this case six indictments have been handed down in the New York City area alleging illegal substitution and mislabeling of generic cyclandelate in prescriptions requiring Cyclospasmol. This we are told constitutes "additional undisputed evidence suggesting that illegal substitution and mislabeling in New York are neither *de minimis* nor inadvertent." Of course it is not disputed that the indictments have been filed but the record does not show any convictions. Six indictments are certainly not proof of any illegality and cannot reasonably be described as undisputed evidence of widespread or deliberate substitution and mislabeling even by the druggists much less by the defendant manufacturers here. If pharmacists are violating state laws which provide criminal sanctions, they should be punished. The criminal actions commenced if anything should discourage unethical pharmacists, and if convictions ensue even the *de minimis* violations adduced on this trial would be further reduced.

Admittedly there has been an imitation of color and capsule and the use of catalogues displaying both the generic and brand name drugs. There was, however, evidence that the catalogue juxtaposition of the drugs was a trade practice.[4]

The majority also contends that the appellees have not offered any "persuasive" evidence of a legitimate reason

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[4] Two defense witnesses, Sperber and Blackman testified that it was common in the industry to list the genric drug next to the brand name drug. In addition, Mr. Lowenkron, a witness for Ives, testified that druggists and doctors refer to drugs by the brand name. Thus, it would seem that juxtaposition of the generic and brand name drug would be imperative for generic manufacturers to compete effectively. See *Pagliero v. Wallace China Co., supra,* 198 F.2d at 343.

unrelated to Cyclospasmol for using identically-colored, look-alike capsules instead of those of a different color, size or shape. However, the trial court which heard the evidence found that the colors were functional in several respects. The court found that many elderly patients associate the appearance of their medication with its therapeutic effects. The court credited testimony that some elderly patients refuse to take equivalent drugs of a different color despite explanations of equivalence by their physicians while others do eventually accept it but experience confusion and anxiety. 488 F.Supp. at 389, 399. The majority does not characterize this finding or other evidence of functionality discussed in the opinion below[5] as "clearly erroneous." This finding was based on the testimony of three physicians and the Chief Pharmacist of a hospital. There is no reason to require the direct evidence of such patients as the majority suggests. Judge Nickerson's findings of fact based upon the testimony of witnesses who appeared before him cannot be disregarded by this court. See, e.g., *Master Shipping Agency, Inc. v. M.S. Farida,* 571 F.2d 131 (2d Cir. 1978).

In sum I am persuaded that Ives has failed on trial to adduce any evidence of substance which would support a finding of a Section 32 violation. I would affirm.

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5 Other evidence which supported Judge Nickerson's finding of functionality of the color included: testimony by physicians that they often give their patients color coded charts to help the patients avoid confusion between several drugs; testimony that color is useful in identifying drug overdoses in emergencies; and evidence which showed that some hospitals and pharmacies refused to purchase green cyclandelate capsules because of a potential for confusion. *Ives Laboratories, Inc. v. Darby Drug Co., Inc., supra,* 488 F.Supp. at 399.

Appendix D

UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse, in the City of New York on the twenty-third day of March, One Thousand Nine Hundred and Eighty-One.

Present:

HONORABLE J. EDWARD LUMBARD,

HONORABLE WALTER R. MANSFIELD,

HONORABLE WILLIAM H. MULLIGAN,

Circuit Judges.

FILED MAR. 23, 1981
A. Daniel Fusaro, Clerk

Dkt. No. 80-7314

IVES LABORATORIES, INC.,
Plaintiff-Appellant,

-against-

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Defendants-Appellees.

Appendix D

Our opinion in the above is corrected as follows:

Slip. Op. page 967, line 12: The word "appellees" is changed to "appellant".

s/ J. Edward Lumbard
J. Edward Lumbard, U.S.C.J.

s/ Walter R. Mansfield
Walter R. Mansfield, U.S.C.J.

s/ William H. Mulligan
William H. Mulligan, U.S.C.J.

APPENDIX E — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, (2D CIR., FEB. 25, 1981)

UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

No. 80-7314

At a stated term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Court House, in the City of New York, on the 25th day of February, one thousand nine hundred and eighty-one.

IVES LABORATORIES, INC.,
Plaintiff-Appellant,

-against-

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Defendants-Appellees.

Filed
Feb. 25, 1981

A petition for rehearing containing a suggestion that the action be reheard in banc having been filed herein by counsel for the defendants-appellees, Darby Drug Co. Inc., et al,

Upon consideration by the panel that heard the appeal, it is

Appendix E

Ordered that said petition for rehearing is DENIED.

It is further noted that the suggestion for rehearing in banc has been transmitted to the judges of the court in regular active service and to any other judge on the panel that heard the appeal and that no such judge has requested that a vote be taken thereon.

s/ A. Daniel Fusaro
A. Daniel Fusaro,
Clerk

APPENDIX F — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, ___ F. SUPP. ___, NO. 78 C 372 (E.D.N.Y. MAY 12, 1981)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

78 C 372

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., INWOOD LABORATORIES, INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants.

COOPER, DUNHAM, CLARK, GRIFFITH & MORAN
(Marie V. Driscoll, Esq., of counsel)
New York, New York
for Ives Laboratories, Inc.

KIRSCHSTEIN, KIRSCHSTEIN, OTTINGER & COBRIN, P.C.
(Peter T. Cobrin, Esq., of counsel)
New York, New York
for Premo Pharmaceutical Laboratories, Inc.

Appendix F

SALON, MARROW AND DYCKMAN
(Robert V. Marrow, Esq., of counsel)
New York, New York
for Darby Drug Co., Inc., MD Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.

BASS, ULMAN & LUSTIGMAN
(Steven R. Trost, Esq., of counsel)
New York, New York
for Inwood Laboratories, Inc.

NICKERSON, District Judge

Plaintiff Ives Laboratories brought suit in this court alleging that defendants violated Sections 32 and 43(a) of the Lanham Act, 15 U.S.C. §§1114 and 1125(a), by manufacturing and distributing a generic drug—cyclandelate— using capsules identical in color, shape, and size to those used by plaintiff in its equivalent trademarked product—Cyclospasmol. This court dismissed the action after a bench trial. On January 8, 1981 the Court of Appeals reversed this court's judgment and remanded for further proceedings consistent with its opinion. Plaintiff now moves for entry of an order on the mandate of the Court of Appeals.

I

Defendants urge the court not to restrain them from selling cyclandelate in blue or blue and red capsules resembling those used for Cyclospasmol. Instead, they ask the court merely to order them to place on or with every container of their cyclandelate products an appropriate warning against labelling the products as Cyclospasmol.

Appendix F

This court reads the majority opinion of the Court of Appeals as requiring this court to grant a permanent injunction giving plaintiff a monopoly over the colors blue and a combination of blue and red for capsules of the same shape and size as those used by plaintiff to sell Cyclospasmol. Certainly a mere notice to pharmacists would not meet the conditions set by the majority opinion of the Court of Appeals. This court's views of the merits of the matter are now irrelevant. The opinion of the Court of Appeals is binding. The injunction to be issued will restrain defendants from selling cyclandelate in capsules that are confusingly similar in color, shape, and size to those now used by plaintiff.

II

Plaintiff asks that the court order defendants to deliver to plaintiff for destruction all the blue and blue and red capsules containing cyclandelate in their possession. Plaintiff also seeks an order directing a recall by defendants of all such capsules sold to customers after January 8, 1981, the date of the Court of Appeals opinion, and a delivery of those capsules to plaintiff for destruction.

Under 15 U.S.C. §1118, where a violation of trademark rights has been established, the court "may order" all receptacles "bearing the registered mark" or any "colorable imitation thereof" to be "delivered up and destroyed."

The court will direct defendants to recall the capsules sold to defendants' customers since January 8, 1981. *Perfect Fit Industries, Inc. v. Acme Quilting Co., Inc.*, Nos. 80-7489, 7585, 7587 (2d Cir. April 13, 1981). Since the defendants' capsules do not bear plaintiff's mark Cyclospasmol, §1118 would not seem to authorize their delivery to plaintiff for destruction. But even if

in equity the court has such power, the court must bear in mind the Second Circuit's admonition that the court should "shape the remedy so as to do as little injury to the defendant as is necessary in order to insure adequate protection to the plaintiff." *Upjohn Company v. Schwartz*, 246 F.2d 254, 262 (2d Cir. 1957) *quoting Artype, Inc. v. Zappulla*, 228 F.2d 695, 698 (2d Cir. 1956) (L. Hand, J.). Plaintiff will be adequately protected if defendants cease to put cyclandelate in capsules of the same color, size, and shape as plaintiff. The cyclandelate can be recovered and placed in capsules of different colors, and the blue and blue and red capsules may be utilized for other products.

III

Plaintiff also seeks damages, profits, and costs. The provisions of 15 U.S.C. §1117 recite that a successful plaintiff in a trademark action "shall be entitled, subject to the provisions of sections 1111 and 1114 of this title, and subject to the principles of equity, to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action." Since the Court of Appeals has directed in its mandate that plaintiff recover costs the court will include such a provision in the order.

The court need not award profits and damages if an injunction will satisfy the equities of the case. *Carl Zeiss Stiftung v. Veb Carl Zeiss Jena*, 433 F.2d 686, 706-07 (2d Cir. 1970), *cert. denied*, 403 U.S. 905 (1971); *Grotrian, Helfferich, Schulz, TH. Steinwag Nachf v. Steinway & Sons*, 523 F.2d 1331, 1344 (2d Cir. 1975). But where the infringer acted with "the deliberate intent to cause confusion, mistake or to deceive purchasers; in other words, to purposely palm off the infringer's goods as those of the infringed," the court is required to award damages and profits. *Carl Zeiss Stiftung v. Veb Carl Zeiss Jena, supra*, 433 F.2d at 707.

The opinion of the Court of Appeals in the present case finds such a deliberate intent. Accordingly, plaintiff may recover its damages and defendants' profits to the extent they are proven. *Perfect Fit Industries, Inc. v. Acme Quilting Co.*, 618 F.2d 950, 955 (2d Cir. 1980).

IV

Plaintiff seeks to recover attorney fees pursuant to the last sentence of 18 U.S.C. §1117 which reads, "The court in exceptional cases may award reasonable attorney fees to the prevailing party." According to the legislative history attorney fees should be awarded to plaintiffs where "the acts of infringement can be characterized as 'malicious,' 'fraudulent,' 'deliberate,' or 'willful.'" S. Rep. No. 93-1400, 93rd Cong., 2nd Sess. *reprinted in* [1974] U.S. Code Cong. & Ad. News 7132, 7133.

Certainly in the light of the dissenting opinion of Judge Mulligan in the present case it cannot be said that defendants asserted their defenses in bad faith or that a gross injustice would be done if attorney fees were denied. Under the circumstances this court deems this case not to be "exceptional" and therefore will not award attorney fees.

An order is entered with this memorandum.

Dated: Brooklyn, New York
May 12, 1981

s/ Eugene H. Nickerson
Eugene H. Nickerson, U.S.D.J.

Appendix F

The Clerk shall make copies of this Memorandum and serve it upon the parties.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

78 C 372

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., INWOOD LABORATORIES, INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants.

ORDER

Plaintiff having appealed to the United States Court of Appeals for the Second Circuit from the judgment entered on April 29, 1980, and the Court having issued a decision on January 8, 1981 reversing the judgment of this court and remanding the case, and defendants' petition for rehearing and rehearing en banc having been denied by the Court on February 25, 1981, and the mandate of the Court having been transmitted and filed in this court on March 10, 1981, in compliance with that mandate it is on motion of plaintiff,

ORDERED, ADJUDGED, AND DECREED:

1. Defendants Darby Drug Co., Inc., Inwood Laboratories, Inc., MD Pharmaceutical Company, Inc. Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc., their officers, agents, servants, employees and all those holding by, through or under them or any of them, and all persons acting in concert or participation with them, including all parents and subsidiary corporations, and successors and assigns, are permanently restrained and enjoined from manufacturing for sale, selling, offering for sale, advertising or promoting the drug cyclandelate in capsules confusingly similar to plaintiff's present Cyclospasmol capsules by reason of their blue or blue and red colors and their size and shape.

2. Upon receiving notice of this judgment each defendant shall make an accurate inventory under oath of all cyclandelate in their possession or under their control in such blue or blue and red capsules as well as any printed material referring to or describing the appearance of said capsules and shall, within 15 days of receipt of notice of this judgment, deliver the inventory list to plaintiff in care of Egon Berg, Esq., American Home Products Corporation, 685 Third Avenue, New York, New York 10017.

3. Defendants shall, not later than 15 days of receipt of the notice of this judgment, at their expense, deliver to an independent mailing concern to be designated by plaintiff, pre-addressed envelopes containing the names and addresses of all wholesalers, distributers, jobbers, pharmacies, and any person, firm or corporation whatsoever to whom defendants, their agents, servants, employees, or attorneys distributed, shipped, offered for sale, or sold, blue or blue and red cyclandelate

capsules after January 8, 1981 so that such mailing concern may mail by first class mail and at defendants' expense, letters notifying those to whom defendants distributed, shipped, offered for sale, or sold blue or blue and red cyclandelate capsules after January 8, 1981 that the capsules may not be used to fill physicians' prescriptions for Cyclospasmol and requesting that all such blue or blue and red capsules be sent immediately to defendants. Defendants shall offer monetary credit for such products, and shall grant such credit for products sent them.

4. Within 10 days after receipt of notice of this judgment defendants shall each make a draft of the notification letter required by paragraph 3 available to plaintiff, and shall advise plaintiff of the number of envelopes to be mailed by the mailing concern, provided that it undertakes in writing to maintain the identity of the names and addresses on the envelopes confidential and not to disclose such identity, directly or indirectly, to plaintiff or any of its agents, servants, attorneys or employees and that the envelopes contain no marking other than the names and addresses and a return address, except that the envelopes shall contain on the front face the notation "IMPORTANT NOTICE" in prominent and readable block letters and shall contain nothing other than the notification.

5. Plaintiff shall recover from the defendants its damages sustained and the defendants' profits derived by reason of defendants' sale of cyclandelate in blue or blue and red capsules simulating the appearance of plaintiff's capsules containing Cyclospasmol. The issues as to the amount of damages and profits shall be tried before this court.

6. Plaintiff shall have judgment against defendants for costs in the Court of Appeals and in this court up to and including the entry of judgment. The costs are to be taxed by the Clerk.

Plaintiff shall submit a verified bill of costs within 20 days after entry of this judgment. This court reserves for further consideration all questions pertaining to damages and profits and to costs relating to proceedings to determine damages and profits.

7. This court retains jurisdiction to assure compliance by defendants and to consider damages and profits and further costs.

Enter.

Dated: Brooklyn, New York
May 12, 1981

s/ Eugene H. Nickerson
Eugene H. Nickerson, U.S.D.J.

The Clerk shall make copies of this Order and serve it upon the parties.

APPENDIX G — ARTICLE I, SECTION 8, CLAUSE 8 OF THE CONSTITUTION OF THE UNITED STATES

"Section 8. The Congress shall have Power . . .

* * *

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . ."

APPENDIX G — THE FIRST AMENDMENT TO THE CONSTITUTION OF THE UNITED STATES

"AMENDMENT [I]

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

APPENDIX G — §32 OF THE LANHAM ACT, 15 U.S.C. §1114

"§1114. Remedies; infringement; innocent infringement by printers and publishers

(1) Any person who shall, without the consent of the registrant—

(a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or

(b) reproduce, counterfeit, copy or colorably imitate a registered mark and apply such reproduction, counterfeit, copy, or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive.

shall be liable in a civil action by the registrant for the remedies hereinafter provided. Under subsection (b) of this section, the registrant shall not be entitled to recover profits or damages unless the acts have been committed with knowledge that such imitation is intended to be used to cause confusion or to cause mistake, or to deceive.

(2) Notwithstanding any other provision of this chapter, the remedies given to the owner of the right infringed shall be limited as follows: (a) Where an infringer is engaged solely in the business of printing the mark for others and establishes that he was an innocent infringer the owner of the right infringed shall be entitled as against such infringer only to an injunction against future printing; (b) where the infringement complained of is contained in or is part of paid advertising matter in a newspaper, magazine, or other similar periodical the remedies of the owner of the right infringed as against the publisher or distributor of such newspaper, magazine, or other similar periodical shall be confined to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar periodical: *Provided,* That these limitations shall apply only to innocent infringers; (c) injunction relief shall not be available to the owner of the right infringed in respect of an issue of a newspaper, magazine, or other similar periodical containing infringing matter when restraining the dissemination of such infringing matter in any particular issue of such periodical would delay the delivery of such issue after the regular time therefor, and such delay would be due to the method by which publication and distribution of such periodical is customarily conducted in accordance with sound business practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction

or restraining order with respect to such infringing matter. July 5, 1946, c. 540, Title VI, §32, 60 Stat. 437; Oct. 9, 1962, Pub. L. 87-772, §17, 76 Stat. 773."

APPENDIX G — §43(a) OF THE LANHAM ACT, 15 U.S.C. §1125(a)

"§1125. False designations of origin and false descriptions forbidden

(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation or origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

(b) Any goods marked or labeled in contravention of the provisions of this section shall not be imported into the United States or admitted to entry at any customhouse of the United States. The owner, importer, or consignee of goods refused entry at any customhouse under this section may have any recourse by protest or appeal that is given under the customs revenue laws or may have the remedy given by this

chapter in cases involving goods refused entry or seized.

July 5, 1946, c. 540, Title VIII, §43, 60 Stat. 441."

APPENDIX G — NEW YORK EDUCATION LAW §§6810; 6815(2)(h), (j); 6816, 6816-a (McKINNEY'S SUPP. 1981)

"§6810. Prescriptions

1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act[1] or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words 'drug' and 'prescription required drug' within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision.

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1. 21 U.S.C.A. §301 et seq.

2. A prescription may not be refilled unless it bears a contrary instruction and indicates on its face the number of times it may be refilled. A prescription may not be refilled more times than allowed on the prescription. The date of each refilling must be indicated on the original prescription. Prescriptions for controlled substances shall be refilled only pursuant to article thirty-three of the public health law.

3. A copy of a prescription for a controlled substance shall not be furnished to the patient but may be furnished to any licensed practitioner authorized to write such prescription. Copies of other prescriptions shall be furnished to the patient at his request, but such copies are issued for the informational purposes of the prescribers only, and shall be so worded.

4. Oral prescriptions for controlled substances shall be filled pursuant to article thirty-three of the public health law. A pharmacist may fill an oral prescription for a drug, other than a controlled substance, made by a practitioner legally authorized to prescribe drugs. An oral authorization for the refill of a prescription, other than a prescription for a controlled substance, may be made by a practitioner legally authorized to prescribe drugs. The pharmacist receiving such oral authorization for the refill of a prescription shall write on the reverse side of the original prescription the date, time, and name of the practitioner authorizing the refill of the prescription.

5. Records of all prescriptions filled or refilled shall be maintained for a period of at least five years and upon request made available for inspection and copying by a representative of the department. Such records shall indicate date of filling or refilling, doctor's name, patient's name and address and the name or initials of the pharmacist who prepared, compounded, or dispensed the prescription. Records of prescriptions for controlled substances shall be maintained pursuant to requirements of article thirty-three of the public health law.

6. (a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing two lines for the prescriber's signature. There shall be a signature line in the lower right hand corner of the prescription form beneath which shall be clearly imprinted the words 'substitution permissible'; there shall be a signature line in the lower left hand corner of the prescription form beneath which shall be clearly imprinted the words 'dispense as written'. The prescriber's signature on either signature line shall validate the prescription and shall designate approval or disapproval of substitution by a pharmacist of a drug product pursuant to paragraph (*o*) of subdivision one of section two hundred six of the public health law. Imprinted conspicuously on the prescription forms shall be the words: 'This prescription will be filled generically unless physician signs on line stating "dispense as written".'

(b) If the prescriber designates approval of substitution he shall inform the patient that the pharmacist will substitute a drug product pursuant to paragraph (*o*) of subdivision one of section two hundred six of the public health law.

(c) The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law.

Added L.1972, c. 881, §5; amended L.1977, c. 776, §2.

§6815. Adulterating misbranding and substituting

* * *

2. Misbranded and substituted drugs and devices. A drug or device shall be deemed to be misbranded:

* * *

h. (1) If it is a drug and its container is so made, formed or filled as to be misleading; (2) if it is an imitation of another drug; (3) if it is offered for sale under the name of another drug; or (4) if it bears a copy, counterfeit, or colorable imitation of the trademark, label, container or identifying name or design of another drug.

* * *

j. Except as required by article thirty-three of the public health law, the labeling provisions of this article shall not apply to the compounding and dispensing of drugs on the written prescription of a physician, a dentist, a podiatrist or a veterinarian, which prescription when filled shall be kept on file for at least five years by the pharmacist or druggist. Such drug shall bear a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription, name and address of the patient and the name of the physician or other practitioner authorized by law to issue the prescription. In addition, such label shall contain the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

As amended L.1972, c. 881, §6; L.1973, c. 752, §1.

§6816. Omitting to label drugs, or labeling them wrongly

1. a. Any person, who, in putting up any drug, medicine, or food or preparation used in medical practice, or making up any prescription, or filling any order for drugs, medicines, food or preparation puts any untrue label, stamp or other designation of contents upon any box, bottle or

other package containing a drug, medicine, food or preparation used in medical practice, or substitutes or dispenses a different article for or in lieu of any article prescribed, ordered, or demanded, except where required pursuant to section sixty-eight hundred sixteen-a of this article, or puts up a greater or lesser quantity of any ingredient specified in any such prescription, order or demand than that prescribed, ordered or demanded, or otherwise deviates from the terms of the prescription, order or demand by substituting one drug for another, except where required pursuant to section sixty-eight hundred sixteen-a of this article, is guilty of a misdemeanor; provided, however, that except in the case of physicians' prescriptions, nothing herein contained shall be deemed or construed to prevent or impair or in any manner affect the right of any apothecary, druggist, pharmacist or other person to recommend the purchase of an article other than that ordered, required or demanded, but of a similar nature, or to sell such other article in place or in lieu of an article ordered, required or demanded, with the knowledge and consent of the purchaser. Upon a second conviction for a violation of this section the offender must be sentenced to imprisonment, for a term of not less than ten days nor more than one year, and to the payment of a fine of not less than ten dollars nor more than five hundred dollars. The third conviction of a violation of any of the provisions of this section, in addition to rendering the offender liable to the

penalty prescribed by law for a misdemeanor, shall forfeit any right which he may possess under the law of this state at the time of such conviction, to engage as proprietor, agent, employee or otherwise, in the business of an apothecary, pharmacist, or druggist, or to compound, prepare or dispense prescriptions or orders for drugs, medicines or foods or preparations used in medical practice; and the offender shall be by reason of such conviction disqualified from engaging in any such business as proprietor, agent, employee or otherwise or compounding preparing or dispensing medical prescriptions or orders for drugs, medicines, or foods or preparations used in medical practice.

b. The provisions of this section shall not apply to the practice of a practioner who is not the proprietor of a store for the dispensing or retailing of drugs, medicines and poisons, or who is not in the employ of such a proprietor, and shall not prevent practitioners from supplying their patients with such articles as they may deem proper, and except as to the labeling of poisons shall not apply to the sale of medicines or poisons at wholesale when not for the use or consumption by the purchaser; provided, however, that the sale of medicines or poisons at wholesale shall continue to be subject to such regulations as from time to time may be lawfully made by the board of pharmacy or by any competent board of health.

c. The provisions of this section shall not apply to a limited pharmacy which prepares a formulary containing the brand names and the generic names of drugs and of manufacturers which it stocks, provided that it furnishes a copy of such formulary to each physician on its staff and the physician signs a statement authorizing the hospital to supply the drug under any generic or nonproprietary name listed therein and in conformity with the regulations of the commissioner of education.

2. For the purposes set forth in this section, the terms prescription, order or demand shall apply only to those items subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter. The written order of a physician for items not subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter shall be construed to be a direction, a fiscal order or a voucher.
As Amended L.1976, c. 76, §14; L.1977, c. 776, §3.

* * *

§6816-a. When substitution is required.

1. A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met:

Appendix G

(a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber places his signature above the words, 'substitution permissible', or in the case of oral prescriptions, the prescriber must expressly state that substitution shall be permitted; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (*o*) of subdivision one of section two hundred six of the public health law; and

(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

2. In the event a patient chooses to have a prescription filled by an out of state dispenser, the laws of that state shall prevail.
Added L.1977, c. 776, §4."

APPENDIX G — NEW YORK PUBLIC HEALTH LAW, §206(1)(o) (McKINNEY'S SUPP. 1981)

"§206. Commissioner; general powers and duties

1. The commissioner shall:

* * *

(o) establish and publish a list of drug products, each of which shall meet the following conditions:

(1) The drug product has been certified or approved by the commissioner of the Federal Food and Drug Administration as being safe and effective for its labeled indications for use, and a new-drug application or an abbreviated new-drug application approved pursuant to the Federal Food, Drug, and Cosmetic Act is held for such drug products; and

(2) The commissioner of the Federal Food and Drug Administration has:

(i) not proposed or promulgated a regulation to establish a bioequivalency requirement for such drug product, or

(ii) proposed a regulation to establish a bioequivalency requirement for such drug product and subsequently has determined not to promulgate such regulation for such drug product, or

(iii) promulgated a regulation to establish a bioequivalency requirement for such drug product and has approved a supplemental application that provides evidence that the drug product meets the bioequivalency requirement."

Office - Supreme Court, U.S.
FILED
JAN 13 1982
ALEXANDER L. STEVAS,
CLERK

No. 80-2182
No. 81-11

In The
Supreme Court of the United States
October Term, 1981

INWOOD LABORATORIES, INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

DARBY DRUG CO., INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

JOINT APPENDIX

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Petition for *Certiorari* Filed June 24, 1981
***Certiorari* Granted October 13, 1981**

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OPINIONS BELOW

The five opinions rendered below were reprinted in the Appendices to the Petition of Inwood Laboratories, Inc. ("Inwood") and Premo Pharmaceutical Laboratories, Inc. ("Premo") for *Certiorari*, No. 80-2182, in chronological order. Pursuant to Supreme Court Rule 33.1, they have not been reproduced again in the joint appendix, and appear in the Appendices to the Petition ("Pet.App.") as indexed below:

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RELEVANT DOCKET ENTRIES IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK PURSUANT TO SUPREME COURT RULE 30.5

Date	Entry
2/28/78	Complaint filed. Summons issued.
	***
3/20/78	Notice of motion returnable 3/31/78, with memo of law and affidavits of H. Lowenkron, S. Baron and M. Altin for a preliminary injunction, filed.
	***
4/13/80	Answer of defendant Premo Pharmaceutical Labs Inc. ("Premo") filed.
	***
5/1/78	Answer of Inwood Laboratories, Inc. ("Inwood"), filed.
	***
5/11/78	Plaintiff's reply to Counterclaim of Darby Drug Co. Inc. ("Darby").
5/15/78	By NICKERSON J. — FINAL DECREE BY CONSENT permanently enjoining LOWITT LABS, INC. from passing off of or substituting cyclandelate capsules from another source as and for plaintiff's CYCLOSPASMOL, etc. See decree.

Relevant Docket Entries

***

Affidavit of Seymour Blackman filed.

Affidavit of Edward Stempel filed.

***

5/16/78 ANSWER and amended complaint of defendants Darby, MD Pharmaceutical Company ("MD"), Rugby Laboratories, Inc. ("Rugby") and Sherry Pharmaceutical Co. ("Sherry"), filed.

Affidavits of Joseph Ashkin, Kent D. Shinbach, and memo of law in opposition to plaintiff's motion for a preliminary injunction, filed.

***

Affidavit in opposition to motion for a preliminary injunction filed with memo.

***

5/19/78 Affidavits of Steven J. Baron, Jay Draper, Richard C. Johnston and Bernard L. Sparta filed.

***

6/6/78 Reply of plaintiff to counterclaim in amended answer of Darby, Sherry, Rugby and MD.

Relevant Docket Entries

Deposition transcript of Inwood filed.

Deposition transcript of Premo filed.

Deposition transcript of Darby, Rugby and Sherry filed.

***

Plaintiff's reply affidavits filed.

***

6/28/78 Second affidavit of Seymour N. Blackman submitted on behalf of defendant Premo in opposition to plaintiff's motion for preliminary injunction, filed.

***

8/02/78 By NICKERSON J. — Memorandum and Order dated 8/2/78, plaintiff's motion for a preliminary injunction are not warranted (see order; copies mailed), filed.

***

8/18/78 By NICKERSON J. — Order denying plaintiff's motion for a preliminary injunction except as to the use of the word CYCLOSPASMOL, etc., filed.

***

Relevant Docket Entries

9/13/78	Notice of appeal filed by plaintiff, filed, copies mailed.
	***
10/06/78	Record on appeal, certified and mailed to Court of Appeals.
	***
7/05/79	Certified copy of mandate received and filed from Court of Appeals affirming decision of District Court, and taxing costs as indicated.
	***
1/15/80	Before NICKERSON J. — Case called. Counsel for both sides present. Trial — Jan. 21 at 9:30 a.m.
	***
1/21/80	Before NICKERSON J. — Case called. Trial ordered & begun. Trial continued to 1/22/80.
1/22/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/23/80.
1/23/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/24/80.
1/24/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/25/80.

Relevant Docket Entries

1/25/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/28/80.
1/28/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/29/80.
1/29/80	Before NICKERSON J. — Case called. Trial resumed. Trial continued to 1/30/80.
1/30/80	Before NICKERSON J. — Case called. Trial resumed. Trial concluded. Parties each move for Judgment. Decision reserved. Brief 2/19/80 — Reply 2/29/80.

***

1/31/80	Pretrial Order, filed.
	Stenographer's transcript dated 1/29/80 filed.
	Stenographer's transcript dated 1/30/80 filed.
2/06/80	Stenographer's transcript dated 1/28/80 filed.
2/08/80	Stenographer's transcript dated 1/25/80 filed.
	Stenographer's transcripts dated 1/21/80, 1/22/80, 1/23/80 & 1/24/80 filed.
2/20/80	By NICKERSON J. — MODIFICATION TO PRETRIAL ORDER dated 2/19/80 as follows: "27. Premo, Inwood & MD are manufacturers that sell cyclandelate capsules principally to

wholesalers, hospitals & retail pharmacies. Premo is a manufacturer that sells cyclandelate capsules principally to wholesalers and hospitals," filed.

***

4/15/80 By NICKERSON J. — Memorandum and Order dated 4/15/80 that the foregoing constitutes the Court's findings of fact and conclusions of law (see Memo & Order). Plaintiff may have judgment permanently enjoining Sherry from using the word "SPASMOL." Otherwise the complaint is dismissed. Filed (copies of this Memo & Order served upon the parties as directed).

***

4/29/80 By NICKERSON J. — JUDGMENT dated 4/28/80 that defendant Sherry is permanently enjoined from directly or indirectly using as a trademark or trade name or component the word "CYCLOSPASMOL" (see Order for details), filed.

***

5/15/80 Notice of Appeal, filed. Copy of Notice & Docket Entries sent to Court of Appeals. Attys. notified.

5/23/80 Corrections to Ives' trial transcript filed.

Relevant Docket Entries

***

6/12/80	Record on Appeal certified and mailed to the Court of Appeals with certified copies of docket entries.
6/16/80	Acknowledgment of receipt on record on appeal dated 6/13/80, filed.
8/11/80	Supplemental Record on Appeal certified and mailed to the Court of Appeals with certified copies of docket entries.

***

8/26/80	Supplemental record #2 submitting plaintiff's exhibits and one defendant's exhibit certified and handed to DAVID STIMSON for delivery to the Court of Appeals, with certified copy of docket entries.
9/08/80	Acknowledgment of receipt of record on appeal from Court of Appeals dated 9/4/80, filed.
3/10/81	Certified copy of mandate from the Court of Appeals that the judgment of the District Court is REVERSED and the action is remanded to said District Court for further proceedings in accordance with the opinion of this Court with costs to be taxed against the appellees. Filed (case reopened and reassigned to Costantino, J. by random selection).

Relevant Docket Entries

3/20/81	Record on Appeal received from Court of Appeals, acknowledgement mailed.
	***
3/30/81	Plaintiff's notice of motion returnable 4/14/81 at 10:00 a.m. for an order of judgment permanently enjoining the defts from selling prescrip. drugs cyclandelate in capsules that are similar in appearance to the capsules in which plaintiff's CYCLOSPASMOL capsules are sold, filed.
4/02/81	Before Costantino, J. — Case called. Counsel for all sides present. Motion for reassignment of this case to J. Nickerson argued. Motion granted. Order to be prepared by Court.
4/13/81	Notice of motion returnable 4/14/81 at 10:00 a.m. for Judgment on the Mandate, filed.
	***
5/15/81	By NICKERSON J. — Memo dated 5/12/81, filed. Party notified.
	By NICKERSON J. — Order dated 5/12/81 that defendants Darby, Inwood, MD, Premo, Rugby and Sherry, etc. are permanently restrained and enjoined from mfg. for sale, selling, offering for sale, advertising or promoting the drug cyclandelate in capsules confusingly similar to plaintiff's present CYCLOSPASMOL capsules by reason of their blue or blue-and-red colors and their size and shape, etc., filed. Clerk to serve

parties with copies of this Order. Parties served as directed.

***

10/16/81 Before NICKERSON J. — Case called. Defendant's motion for a stay argued. Stay on injunction denied. Plaintiff consents to stay on further proceedings.

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK — PLAINTIFF'S COMPLAINT FILED FEBRUARY 28, 1978

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.

Plaintiff,

v.

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, LOWITT LABS., INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.

Defendants.

COMPLAINT FOR TRADEMARK INFRINGEMENT AND UNFAIR COMPETITION

1. Plaintiff, Ives Laboratories, Inc., is a corporation organized and existing under the laws of the State of New York with its principal place of business at 685 Third Avenue, City, County and State of New York 10017.

2. Upon information and belief, Darby Drug Co., Inc. ("Darby"), is a New York corporation with a place of business at 100 Banks Avenue, Rockville Center, County of Nassau, New York 11570.

3. Upon information and belief, Inwood Laboratories Incorporated ("Inwood"), is a New York corporation with a place of business at 300 Prospect Street, Town of Hempstead, County of Nassau, Inwood, New York 11696.

4. Upon information and belief, Lowitt Labs., Inc. ("Lowitt"), is a New York corporation with a place of business at 68-19 Rockaway Bench Boulevard, Queens, New York.

5. Upon information and belief, MD Pharmaceutical Company, Inc. ("MD"), is a California corporation with a place of business at 3501 W. Cary Avenue, Santa Ana, California 92704.

6. Upon information and belief, Premo Pharmaceutical Laboratories, Inc. ("Premo"), is a New York corporation with a place of business at South Hackensack, New Jersey.

7. Upon information and belief, Rugby Laboratories, Inc. ("Rugby"), is a New York corporation with a place of business at 100 Banks Avenue, Rockville Centre, County of Nassau, New York 11570.

8. Upon information and belief, Sherry Pharmaceutical Co., Inc. ("Sherry"), is a New York corporation with a place of business at 233 West Broadway, Inwood, Town of Hempstead, County of Nassau, New York 11696.

9. Upon information and belief, all defendants are licensed to do business and/or are doing business and/or transacting business in this judicial district.

Complaint

COUNT ONE AGAINST DEFENDANT SHERRY

10. This is a civil action for (a) infringement of a trademark registered in the United States Patent and Trademark Office, (b) unfair competition in the use of a trademark confusingly similar to a trademark previously used by plaintiff, (c) false designation of the origin of goods and false representation or description of goods in or affecting interstate commerce, (d) unconscionable predatory commercial practices, and (e) violation of Section 568(d), Article 24 of the New York General Business Law, of which this Court has jurisdiction under Title 15, United States Code, Sections 1121 and 1125(a); and under Title 28, United States Code, Sections 1338(a) and 1338(b). Jurisdiction additionally arises under United States Code, Title 28, Section 1332, in that this is an action between citizens of different states in which the matter in controversy exceeds, exclusive of interest and costs the sum or value of ten thousand ($10,000) dollars.

11. Since at least 1958 and long prior to the acts of the defendants, complained of herein, plaintiff, which term includes its predecessors in business and title, has been and now is manufacturing, advertising, offering for sale and selling in interstate commerce the prescription drug 3,5,5 trimethyleyclohexyl mandelate thereinafter identified by its generic name "cyclandelate") which is an orally acting peripheral vasodilator, and long prior to the acts complained of herein said preparation has been sold and is now being offered for sale by plaintiff in interstate commerce and in the State of New York, including this judicial district.

12. Continually, since long prior to the acts of the defendants, complained of herein, plaintiff has marketed such cyclandelate in capsule form — a 200 mg. pale blue capsule under the trademark CYCLOSPASMOL and a 400 mg. pale

blue/red capsule under the trademark CYCLOSPASMOL. A photograph of each of said capsules is annexed hereto as Exhibit A, and a bottle label for each of said two dosage forms bearing the trademark CYCLOSPASMOL is annexed as Exhibit B-1 and B-2.

13. Since about 1962, when interstate distribution of plaintiff's capsules first commenced, as aforesaid, both dosage forms of said drug have been marketed in compliance with the laws of the United States and of the various states and with the approval of the U.S. Food and Drug Administration.

14. Upon the introduction of plaintiff's cyclandelate vasodilator product upon the market, and continuously thereafter, it became and now is widely known and recognized by the said trademark CYCLOSPASMOL, and said trademark CYCLOSPASMOL is closely and universally associated with said product as means by which it has become known to physician's, the pharmaceutical trade and patients and its origin identified.

15. The trademark CYCLOSPASMOL is duly registered in the United States Patent and Trademark Office as follows:

Registration No.	Issued
602,919	March 8, 1955 (renewal 1975)

Said registration is now outstanding, validly subsisting, incontestable and uncancelled and plaintiff is the owner thereof. A copy of said registration is annexed hereto as plaintiff's Exhibit C.

Complaint

16. Since long prior to the acts of the defendants complained of herein, plaintiff's CYCLOSPASMOL vasodilator product is and continues to be among the best known and most widely prescribed products in its field. From 1967 through 1976, alone, plaintiff has marketed throughout the United States and has sold (at wholesale value) in excess of seventy million dollars ($70,000,000) of its CYCLOSPASMOL vasodilator products.

17. Since long prior to the acts of the defendants, complained of herein, plaintiff's CYCLOSPASMOL vasodilator products have been extensively advertised and promoted on a nation-wide basis, and plaintiff has invested substantial amounts of time, effort and other resources in bringing to the attention of the medical profession the excellent quality and therapeutic characteristics of such products.

18. By reason of the extensive sales, advertising and promotion of plaintiff's CYCLOSPASMOL vasodilator products and the excellent quality of such products, plaintiff enjoys and has long enjoyed an exceedingly valuable good will in that trademark among physicians, the pharmaceutical trade and patients.

19. Continuously, since in or about 1962, plaintiff has identified its CYCLOSPASMOL cyclandelate capsules in their most widely prescribed strength (200 mg.) by means of a distinctive pale blue capsule dress.

20. Continuously, since about 1975, when plaintiff first introduced its 400 mg. dose of CYCLOSPASMOL cyclandelate capsules, plaintiff has identified such capsules by means of a distinctive capsule dress whereby half of the capsule is colored red and the other half is colored pale blue.

21. The aforesaid trade dress of said capsules, namely the pale blue color of the 200 mg. capsule and the pale blue/red 400 mg. capsule, are arbitrary and non-functional and are intended to identify the respective products of plaintiff to physicians, pharmacists and to patients.

22. Since long prior to the acts of the defendants, complained of herein, the aforesaid cyclandelate products of plaintiff have long been and are now extensively advertised and promoted on a nation-wide basis to physicians and to the pharmaceutical trade. Such advertising and promotional activity has been for the purpose of acquainting physicians with the high quality and therapeutic characteristics of plaintiff's cyclandelate products so that the physician may with full knowledge and confidence prescribe plaintiff's CYCLOSPASMOL, vasodilator to his patients. The aforesaid arbitrary, non-functional and distinctive trade dress of plaintiff's cyclandelate products are among the best known of all trade dresses in the field of vasodilator drugs and as a result thereof, plaintiff's CYCLOSPASMOL products are well known by their distinctive trade dress and have come to be and are recognized as indicia of origin with plaintiff, and patients have come to rely upon said distinctive trade dress as an indication that they are receiving the product of plaintiff which has been prescribed for them by their physician.

23. By reason of the quality and effectiveness of plaintiff's cyclandelate products, and as a result of the long continued and extensive sale, advertising and promotion of said products and their aforesaid arbitrary, non-functional and distinctive trade dress, plaintiff's cyclandelate products now enjoy and have long enjoyed an exceedingly valuable good will among physicians, the pharmaceutical trade and patients, which good will has been and

is of great value to plaintiff in the conduct of its business, and which good will is symbolized by the aforesaid arbitrary, non-functional and distinctive trade dress of said cyclandelate products.

24. Upon information and belief, with full knowledge of the distinctiveness and widespread recognition of plaintiff's trademark CYCLOSPASMOL, defendant Sherry is advertising, promoting and selling in the State of New York, including within this judicial district and in interstate commerce, cyclandelate as a vasodilator under the trademark SPASMOL which is a colorable imitation of plaintiff's trademark CYCLOSPASMOL. A photocopy of page 11, from defendant Sherry's 1977 catalog offering for sale cyclandelate under the trademark SPASMOL, is annexed as Exhibit D.

25. Upon information and belief, defendant Sherry has simulated plaintiff's trademark CYCLOSPASMOL with intent to deceive customers, to appropriate plaintiff's good will and to divert unfairly to defendant Sherry trade which would otherwise have come to plaintiff.

26. The trademark SPASMOL is a colorable imitation of CYCLOSPASMOL and its use by defendant Sherry for a cyclandelate vasodilator product is likely to cause confusion, mistake or to deceive purchasers and is an infringement of plaintiff's trademark CYCLOSPASMOL as applied to a cyclandelate product.

27. Defendant Sherry's use of the trademark SPASMOL is made without the consent of plaintiff to the detriment of plaintiff's interstate and local trade in its cyclandelate products.

28. Upon information and belief, the trademark SPASMOL used by defendant Sherry is calculated to cause confusion, mistake or deceive and has actually confused and deceived the purchasing public into believing that defendant Sherry's cyclandelate product is plaintiff's CYCLOSPASMOL cyclandelate product or a product originating with plaintiff or sponsored or associated with plaintiff.

29. Defendant Sherry's use of the trademark SPASMOL for its cyclandelate product is likely, when applied to the goods of defendant Sherry, to cause confusion or mistaken identity or to deceive purchasers into the belief that such products are the products of plaintiff or that defendant Sherry and its products are endorsed by plaintiff or are sponsored by plaintiff, and defendant Sherry's use of said trademark SPASMOL constitutes unfair competition by defendant Sherry with plaintiff.

30. The defendant Sherry has willfully and knowingly performed and continues to perform the aforesaid acts which infringe upon plaintiff's common law and statutory trademark rights, constitute unfair competition with the plaintiff, and have caused, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business, good will and reputation and plaintiff is without an adequate remedy at law.

COUNT TWO AGAINST DEFENDANTS DARBY, INWOOD, MD, PREMO, RUGBY AND SHERRY

31. Plaintiff repeats and realleges paragraphs 1 through 29, hereinabove, as though fully alleged herein.

32. Defendants Darby, Inwood, MD, Premo, Rugby and Sherry have deliberately embarked upon a course of conduct

which is deceptive, illegal and unfair and which has as its purpose and effect to compete unfairly with plaintiff in the sale of cyclandelate capsules of the same distinctive trade dress as plaintiff's cyclandelate capsules and to cause plaintiff competitive injury.

33. Said defendants Darby, Inwood, MD, Premo, Rugby and Sherry have sold and sell in the State of New York, including within this judicial district and in interstate commerce, prescription drugs, the active ingredient of which is cyclandelate, in both 200 mg. and 400 mg. capsule dosage forms. The aforesaid 200 mg. cyclandelate capsules sold by Darby, Rugby and Sherry have been and/or are being manufactured by Inwood, MD and Premo and sold by each of them, either directly to retailers or to wholesalers such as Darby, Rugby and/or Sherry and/or purchased by Sherry from Darby, Rugby and/or other wholesalers, are a pale blue color, and deceptively simulate the trade dress of plaintiff's aforesaid 200 mg. pale blue CYCLOSPASMOL cyclandelate capsules, and the aforesaid 400 mg. cyclandelate capsules which are manufactured by Inwood and Premo and sold by each of them, either directly to retailers or to wholesalers such as Darby, Rugby and/or Sherry and/or purchased by Sherry from Darby, Rugby and/or other wholesalers, are one half pale blue and the other red and deceptively simulate the trade dress of plaintiff's aforesaid 400 mg. blue/red CYCLOSPASMOL cyclandelate capsules. A photograph displaying plaintiff's 200 mg. and 400 mg. cyclandelate capsules and said defendants' 200 mg. and 400 mg. cyclandelate capsules is attached hereto as Exhibit E.

34. Both dosage forms of the aforesaid cyclandelate capsules of defendants Darby, Inwood, MD, Premo, Rugby and Sherry are being marketed in interstate commerce without

approval of the U.S. Food and Drug Administration (FDA), in violation of Title 21, United States Code, Section 355(a).

35. Said defendants Darby, Inwood, MD, Premo, Rugby and Sherry could have used, had they chosen so to do, other colors and configurations for their cyclandelate products rather than deliberately adopt the trade dress used by plaintiff and the appearance of said defendants' products so deceptively simulate the arbitrary, non-functional and distinctive trade dress of plaintiff's cyclandelate products as to be likely to cause confusion, or to cause mistake, or to deceive.

36. By their manufacture and/or sale of said cyclandelate capsules slavishly imitative of the trade dress of the aforesaid cyclandelate capsules of plaintiff, defendants Darby, Inwood, MD, Premo, Rugby and Sherry have willfully and deliberately engaged in a scheme and course of conduct to place into the hands of the pharmaceutical trade an instrument of fraud whereby cyclandelate drug preparations, not having their source with plaintiff, which are intended to be, can be, and will be passed or palmed off and substituted to the patient as and for the products of plaintiff.

37. The acts of passing off and trademark infringement by defendant Lowitt are being aided and induced by defendants Darby, Inwood, MD, Premo, Rugby and Sherry's manufacture and/or sale of cyclandelate capsules that deceptively imitate the trade dress of plaintiff's 200 mg. and 400 mg. cyclandelate capsules.

38. By their said acts complained of, defendants Darby, Inwood, MD, Premo, Rugby and Sherry have completed unfairly with plaintiff and unfairly traded upon plaintiff's good will and reputation.

39. The aforesaid acts of unfair competition of defendants Darby, Inwood, MD, Premo, Rugby and Sherry have been without the consent of plaintiff and to the detriment of plaintiff's good will in interstate and local trade.

40. The acts of defendants Darby, Inwood, MD, Premo, Rugby and Sherry, as aforesaid, have damaged plaintiff irreparably, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business, good will and reputation and plaintiff is without an adequate remedy at law.

COUNT THREE AGAINST DEFENDANTS DARBY, INWOOD, MD, PREMO, RUGBY AND SHERRY

41. Plaintiff repeats and realleges paragraphs 1 through 3, 5 through 29 and 31 through 38, hereinabove, as though fully alleged herein.

42. Defendants Darby, Inwood, MD, Premo, Rugby and Sherry have advertised, represented, and/or caused or encouraged each other and others to advertise and represent, that their 200 mg. cyclandelate capsules are comparable or equivalent to plaintiff's 200 mg. CYCLOSPASMOL cyclandelate capsules and that their 400 mg. cyclandelate capsules are comparable or equivalent to plaintiff's 400 mg. CYCLOSPASMOL cyclandelate capsules.

43. As hereinabove alleged, the 200 mg. cyclandelate capsules of defendants Darby, Inwood, MD, Premo, Rugby and Sherry are not comparable or equivalent to plaintiff's 200 mg. CYCLOSPASMOL cyclandelate capsules and the 400 mg. cyclandelate capsules of said defendants are not comparable or

equivalent to plaintiff's 400 mg. CYCLOSPASMOL cyclandelate capsules.

44. The aforesaid advertisements and representations of defendants Darby, Inwood, MD, Premo, Rugby and Sherry constitute false representations used in connection with their 200 mg. and 400 mg. capsules within the meaning of Title 15, United States Code, Section 1125(a).

45. Defendants Darby, Inwood, MD, Premo, Rugby and Sherry, with knowledge of the falsity of the aforesaid representations used in connection with said goods, have caused such goods to be transported or used in commerce in violation of said Section 1125(a) of Title 15, United States Code.

46. The acts of defendants Darby, Inwood, MD, Premo, Rugby and Sherry, as aforesaid, have damaged plaintiff irreparably, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business, good will and reputation and plaintiff is without an adequate remedy at law.

COUNT FOUR AGAINST DEFENDANT LOWITT

47. Plaintiff repeats and realleges paragraphs 1 through 4, 9 through 29 and 31 through 38, hereinabove, as though fully alleged herein.

48. A written prescription for CYCLOSPASMOL capsules was presented to Lowitt Labs, Inc., a retail pharmacy located at 69-19 Rockaway Beach Blvd., Queens, New York. Defendant Lowitt failed to fill the written prescription with CYCLOSPASMOL, passing off and substituting instead generic

cyclandelate capsules, although, labelling such prescription bottle CYCLOSPASMOL, said generic cyclandelate capsules simulating the trade dress of plaintiff's CYCLOSPASMOL capsules.

49. Defendant Lowitt's aforesaid acts constitutes trademark infringement and unfair competition with plaintiff.

50. By the aforesaid acts, defendant Lowitt has competed unfairly with plaintiff and unfairly traded upon plaintiff's good will and reputation.

51. Defendant Lowitt's aforesaid acts of trademark infringement and unfair competition are and have been without the consent or license of plaintiff and to the detriment of plaintiff's goodwill in interstate and local trade.

52. By the aforesaid acts, defendant Lowitt has damaged plaintiff irreparably, and if not terminated, will continue to cause irreparable damage and injury to plaintiff's business and goodwill, and plaintiff is without an adequate remedy at law.

COUNT FIVE AGAINST ALL DEFENDANTS

53. Plaintiff repeats and realleges paragraphs 1 through 29, 31 through 38, 42 through 45 and 48 through 50, inclusive hereinabove as though fully alleged herein.

54. Defendants' aforesaid acts complained of are all in violation of Section 368(d), Article 24 of the New York General Business Law.

55. Defendants' acts, as aforesaid, have damaged plaintiff irreparably, and if not terminated, will continue to cause

irreparable damage and injury to plaintiff's business good will and reputation and plaintiff is without an adequate remedy at law.

WHEREFORE, plaintiff prays for judgment as follows:

A. That defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them or any of them in holding by, through or under them or acting under the authority of or in privity with them, and each and all of them, be preliminarily and permanently enjoined from directly or indirectly:

(i) using the word SPASMOL or any colorable imitation thereof, whether alone or together with other terms, in connection with the sale of pharmaceutical preparations;

(ii) printing, publishing, distributing, displaying, offering for sale, or advertising, or in any other way using for the purpose of selling or advertising pharmaceutical preparations, the word SPASMOL or any colorable imitation thereof, whether alone or together with other terms or designs;

(iii) using the word SPASMOL or any word or trademark confusingly similar thereto, in any manner which has or may reasonably have the effect of injuring plaintiff's business reputation or of diluting plaintiff's trademark.

(iv) manufacturing, distributing, advertising, promoting, offering for sale or selling

cyclandelate containing products which in appearance colorably imitate or deceptively simulate the arbitrary, non-functional and distinctive appearance of plaintiff's cyclandelate products; and

(v) continuing the acts of unfair competition, false representations and unconscionable predatory commercial practices herein complained of, or from otherwise competing unfairly with plaintiff, or from doing any acts that may cause the cyclandelate products of defendants Darby, Inwood, MD, Premo, Rugby and Sherry to be mistaken for or confused with or substituted for or passed off as plaintiff's cyclandelate products and/or aiding or inducing others to commit any of the foregoing.

B. That defendants be required to deliver up to this Court for destruction: (i) all existing stocks in their possession or under their control, and lots which can be recalled or recovered from the trade of cyclandelate products having an appearance which is similar to the arbitrary, non-functional and distinctive appearance of plaintiff's cyclandelate products, (ii) all packages, package inserts, labels, labelling, and any other written or printed materials in their posession or under their control which display or show capsules the appearance and configurations of which are similar to the arbitrary, non-functional and distinctive appearance of plaintiff's cyclandelate capsules, or which bear the statements "comparable to CYCLOSPASMOL", "equivalent" or any statements of similar import that may be likely to cause confusion, or to cause mistake, or to deceive purchasers or others, and (iii) all advertising and promotional material,

package inserts, labels, tags, cartons, boxes, containers, brochures, pamphlets, tear sheets, specification sheets, purchase orders, invoices, letterheads, and any other material of any type bearing the word SPASMOL, whether alone or together with other terms or designs.

C. That defendants be ordered to file with this Court and to serve upon plaintiff, within thirty (30) days after service upon defendants of the decree of injunction issued by the Court in this action, a report in writing under oath setting forth in detail the manner and form in which defendants have complied with such injunction.

D. That defendants be required to account to plaintiff for any and all profits derived by them and all damages sustained by plaintiff, by reason of the acts of infringement, unfair competition, false representations and unconscionable commercial practices, hereinabove complained of, and that the damages herein be trebled pursuant to Section 35 of the United States Trademark Act of 1946 (15 U.S.C. §1117).

E. That defendants be required to pay to plaintiff the costs and disbursements of this action including reasonable attorneys fees.

F. That plaintiff have such other and further relief as to the Court may seem just and equitable.

By Egon E. Berg
Egon E. Berg
685 Third Avenue
New York, New York 10017
(212) 986-1000 - Ext. 291

OF COUNSEL:

Vito V. Bellino
Mortimer Altin
Steven Baron

685 Third Avenue
New York, New York
Dated: February 28, 1978

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK — FINAL DECREE BY CONSENT, FILED MAY 15, 1978

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff

vs.

DARBY DRUG CO., INC. et al.,

Defendants.

FINAL DECREE BY CONSENT

Plaintiff Ives Laboratories, Inc. having filed its complaint herein on the 28th day of February, 1978; and defendant Lowitt Labs, Inc. having appeared, and affidavits having been filed by plaintiff in support of a preliminary injunction herein, and defendants having been given an opportunity for discovery, and Lowitt Labs, Inc. having admitted performing the acts complained of against it in the complaint, and having consented to the entry of this decree; and Ives Laboratories, Inc. having moved the Court for the injunction set forth in this decree, having consented to the entry of said decree, and having waived its claim to damages against defendant Lowitt Labs, Inc.; it is therefore

Final Decree by Consent

ORDERED, ADJUDGED AND DECREED that the Court has jurisdiction of the subject matter herein, and of plaintiff Ives Laboratories, Inc. and defendant Lowitt Labs, Inc.; and it is further

ORDERED, ADJUDGED AND DECREED that defendant Lowitt Labs, Inc., and each and all of its officers, agents, servants, and employees, and all persons in active concert or participation with them or any of them, or holding by, through or under them or acting under the authority of or in privity with them, be permanently enjoined from passing off or substituting cyclandelate capsules from another source as and for plaintiff's CYCLOSPASMOL capsules and from using plaintiff's trademark CYCLOSPASMOL or any other name or mark so similar thereto as to be likely to cause confusion, mistake, or deception, to identify products from a source other than plaintiff; and it is further

ORDERED, ADJUDGED AND DECREED that neither party consenting to this decree shall have or recover damages or costs against each other in this action; and it is further

ORDERED, ADJUDGED AND DECREED that this decree cannot be used for advertising purposes; and it is further

ORDERED, ADJUDGED AND DECREED that this Court retains jurisdiction over defendant Lowitt Labs, Inc. to enforce the terms of this decree.

Dated: Brooklyn, New York
May 12, 1978

s/ Eugene H. Nickerson
UNITED STATES DISTRICT JUDGE

Final Decree by Consent

Plaintiff hereby consents to the issuance and entry of a final judgment herein against defendant Lowitt Labs, Inc. in the form and content as set forth above without further notice.

Dated: May 11, 1978

ROGERS HOGE & HILLS

s/ William
Attorneys for Plaintiff

Defendant Lowitt Labs, Inc. hereby consents to the issuance and entry of a final decree in form and content as set forth above without further notice.

Dated: May 10, 1978

LOWITT LABS, INC.

s/ Norman D. Lazar, pres.
Title: President

JACOBSON & GOLDBERG

s/ Arthur Goldberg
Attorneys for Lowitt Labs, Inc.
591 Stewart Avenue
Garden City, New York 11530

[Verification omitted in printing]

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK —PRETRIAL ORDER, FILED JANUARY 31, 1980

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

PRETRIAL ORDER

I. Jurisdictional Basis for the Litigation:

This is an action in which plaintiff alleges that the sale by defendants of look-alike prescription drug capsules constitutes a false designation of origin or false representation in violation of Section 43(a) of the federal Trademark Act, 15 U.S.C. §1125(a); constitutes common law trademark infringement and unfair competition under the laws of the State of New York; and is a violation of New York's anti-dilution statute, General Business Law §368(d). Plaintiff also claims that the defendants are liable for trademark infringement and unfair competition, as contributory infringers, for the infringement of plaintiff's federally registered trademark CYCLOSPASMOL, pursuant to 15 U.S.C. §1114. Plaintiff, in addition, alleges that defendants

are guilty of unfair competition and of a violation of Section 43(a) for representing that their generic cyclandelate is equivalent to plaintiff's CYCLOSPASMOL cyclandelate. Finally, plaintiff claims that Sherry's use of SPASMOL was an infringement of its federally registered trademark CYCLOSPASMOL.

This Court has jurisdiction of these claims pursuant to 28 U.S.C. §§1331 and 1338.

II. Stipulated Facts:

The parties, while reserving objections to their relevance or admissibility, stipulate to the following facts:

A. The Parties:

1. Plaintiff, Ives Laboratories, Inc., (hereinafter "Ives") is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 685 Third Avenue, New York, New York.

2. Defendant, Darby Drug Co., Inc., (hereafter "Darby") is a corporation organized and existing under the laws of the State of New York, with a place of business at 100 Banks Avenue, Rockville Center, New York.

3. Defendant, Inwood Laboratories Incorporated, (hereafter "Inwood") is a corporation organized and existing under the laws of the State of New York, with a place of business at 300 prospect Street, Inwood, New York.

4. Defendant, MD Pharmaceutical Company, Inc., (hereafter "MD") is a corporation organized and existing under

the laws of the State of California, with a place of business at 3501 W. Gary Avenue, Santa Ana, California.

5. Defendant, Premo Pharmaceutical Laboratories, Inc., (hereafter "Premo") is a corporation organized and existing under the laws of the State of New York, with a place of business in South Hackensack, New Jersey.

6. Defendant, Rugby Laboratories, Inc., (hereafter "Rugby") is a corporation organized and existing under the laws of the State of New York, with a place of business at 100 Banks Avenue, Rockville Center, New York.

7. Defendant, Sherry Pharmaceutical Co., Inc., (hereafter "Sherry") is a corporation organized and existing under the laws of the State of New York, with a place of business at 233 West Broadway, Inwood, New York.

8. The named defendant, Lowitt Labs., Inc., having signed a consent decree wherein it admitted the acts complained of and consented to an injunction, is no longer a party to this action.

B. Plaintiff's Product:

9. Ives sells cyclandelate under the trademark CYCLOSPASMOL.

10. The CYCLOSPASMOL trademark is registered in the United States Patent and Trademark Office under Registration No. 602,919. Patent and Trademark Office records show that the registration is valid and subsisting, is incontestable, and is owned by Ives.

Pretrial Order

11. CYCLOSPASMOL cyclandelate is sold by Ives in three dosage forms:

a. 100 mg. tablet in pale orange

b. 200 mg. capsule in blue

c. 400 mg. capsule in red/blue combination

12. The active ingredient in the cyclandelate product is the subject of United States Patent No. 2,707,193. The patent expired in 1972. The patent claimed only the chemical composition of the active ingredient, and did not refer to the form in which the product was to be sold.

13. Ives obtained approval from the Food and Drug Administration of its New Drug Application covering the 200 mg. CYCLOSPASMOL cyclandelate in 1962. (Defendants Premo, Sherry, Darby, Rugby and MD object to this as irrelevant).

14. Ives obtained approval from the Food and Drug Administration of its New Drug Application covering the 400 mg. CYCLOSPASMOL cyclandelate in 1974. (Defendants Premo, Sherry, Darby, Rugby and MD object to this as irrelevant).

15. Ives has been selling CYCLOSPASMOL cyclandelate in the 200 mg. form since 1962 and in the 400 mg. form since 1975.

16. The blue and blue/red colors of the capsules are not dictated by the drug within the capsules, said drug being a white powder.

17. All CYCLOSPASMOL cyclandelate capsules sold by Ives show the name Ives and the NDC number 4148 (400 mg.) or 4124 (200 mg.).

18. CYCLOSPASMOL cyclandelate is marketed as a peripheral vasodilator product used for the treatment and management of peripheral and cerebral vascular diseases.

19. Vasodilators are maintenance drugs, used by patients over long periods of time.

20. Cyclandelate can be dispensed only by prescription.

21. Ives sells CYCLOSPASMOL cyclandelate to wholesalers, retail pharmacists, and hospitals.

22. The advertising and promotion of CYCLOSPASMOL cyclandelate is primarily to prescribing physicians and is not to the general public.

23. A large number of patients for whom peripheral vasodilators are prescribed are elderly and have diminishing visual acuity, i.e. cannot see well.

24. Employees or agents of plaintiff presented to various pharmacies prescriptions for CYCLOSPASMOL (to be dispensed as written) that were filled by the pharmacies with generic cyclandelate rather than CYCLOSPASMOL. In some instances the prescriptions, containing generic cyclandelate, were labelled CYCLOSPASMOL. Copies of the respective prescriptions and the prescription bottles as dispensed are identified in this Pretrial Order as Plaintiff's Exhibits 32(a) through (m).

25. The pharmacies referred to in paragraph 24 were selected from shops at the suggestion of employees of Ives because they thought these pharmacies might be making illegal substitutions in filling prescriptions for CYCLOSPASMOL.

C. Defendants Businesses and Products:

26. All of the defendants sell generic cyclandelate capsules.

27. Premo, Inwood and MD are manufacturers that sell cyclandelate capsules principally to wholesalers, hospitals and retail pharmacies.

28. Defendant Premo first offered for sale and sold its blue 200 mg. cyclandelate capsule and its blue/red 400 mg. cyclandelate capsule in 1976.

29. Inwood first offered for sale and sold its 200 mg. cyclandelate capsule and its 400 mg. cyclandelate capsule in June of 1976.

30. Darby, Rugby, and Sherry are wholesalers that purchase cyclandelate capsules and resell them primarily to physicians and retail pharmacies.

31. All of the defendants except MD sell cyclandelate in two dosage forms, a 200 mg. capsule which is blue and a 400 mg. capsule which is blue/red. MD sells only the 200 mg. in a blue capsule.

32. The colors of the defendants' cyclandelate capsules are identical to the blue and blue/red colors used by plaintiff.

33. At the commencement of this litigation, all of the defendants sold cyclandelate capsules bearing no imprint. Premo began to use the word Premo on its capsules in or about July 1978, after commencement of this suit. On or about July 26, 1979, Inwood imprinted NDC #258 on its 400 mg. cyclandelate capsule, and on or about August 6, 1979, Inwood imprinted NDC 258 on its 200 mg. cyclandelate capsule.

34. The copying of the colors of plaintiff's CYCLOSPASMOL cyclandelate capsules by the defendant manufacturers was intentional.

35. Defendants' respective names are on the labels of bottles of cyclandelate capsules emanating from each of them.

36. It is not the practice of pharmacists to dispense prescription capsules, including cyclandelate capsules, in their original bottles. Pharmacists rebottle such capsules when filling prescriptions, and apply their own labels to those bottles.

37. The defendants have done no clinical investigations or clinical testing in connection with the cyclandelate products sold by them. (This has been ojected to as irrelevant).

38. Plaintiff will not claim in this litigation that the cyclandelate sold by the defendants does not contain the same active ingredient as the CYCLOSPASMOL cyclandelate sold by the plaintiff.

39. Sherry has used SPASMOL as a trademark for the cyclandelate distributed by it. Although Sherry had already ceased use of that trademark, this Court entered a preliminary injunction against use of SPASMOL pending final determination of this suit.

D. Regulatory Agencies:

40. There are published in the May 25, 1979 issue of the Federal Register a notice of a proposal by the Food and Drug Administration to withdraw approval of new drug applications for all peripheral vasodilators. Cyclandelate is one of several products to which the notice applies. (This has been objected to as irrelevant by all defendants except Inwood).

41. Ives has filed a Request for Hearing with the FDA in connection with the above-identified notice. (This has been objected to as irrelevant).

42. Premo has filed a Request for Hearing with the FDA in connection with the above-identified notice. Its request relates to several vasodilators now sold by Premo, or which Premo contemplates selling in the future, including isoxuprine hydrochloride, cyclandelate, tolazoline hydrochloride, nicotinyl alcohol and nylidrin hydrochloride. (This has been objected to as irrelevant).

43. The National Association of Pharmaceutical Manufacturers ("NAPM"), on behalf of its members, which includes the defendants, filed a Request for Hearing regarding the above-identified notice. Its request relates to several vasodilators now sold by NAPM's members, and which NAPM's members contemplate selling in the future, including isoxuprine hydrochloride, cyclandelate, totazoline hydrochloride, nicotinyl alcohol and nylidrin hydrochloride. (This has been objected to as irrelevant by all defendants except Inwood).

III. Exhibits to be Offered in Evidence:

A. Plaintiff's Exhibits:

1. United States Patent No. 2,707,193 for cyclandelate.

2. Cyclandelate powder.

3. Specimen gelatine capsules.

4. CYCLOSPASMOL 100 mg. tablets.

5. Parke-Davis industrial products color wheel.

6. Scherer Hardshell Capselector. (Reserve right to object).

7. Box and bottle of CYCLOSPASMOL, 200 mg.

8. Box and bottle of CYCLOSPASMOL, 400 mg.

9. Examples of Promotional Material for CYCLOSPASMOL cyclandelate distributed by Ives. (Reserve right to object).

10. Examples of advertising in professional journals for CYCLOSPASMOL cyclandelate.

11. Blister pack of five individual capsules of CYCLOSPASMOL, 200 mg. (Object without foundation).

12. Blister pack of five individual capsules of CYCLOSPASMOL, 400 mg. (Object without foundation).

13. Physician's sample of box and bottle of CYCLOSPASMOL, 200 mg. (Object without foundation).

14. Physician's sample of box and bottle of CYCLOSPASMOL, 400 mg. (Object without foundation).

15. Samples of Inwood laboratories, Inc. cyclandelate, 200 mg. (Inwood reserves the right to object to Exhibits 15 and 16 unless such samples bear Inwood's NDC imprint).

16. Samples of Inwood Laboratories, Inc. cyclandelate, 400 mg. (Inwood reserves the right to object to Exhibits 15 and 16 unless such samples bear Inwood's NDC imprint).

17. Samples of MD Pharmaceutical Co., Inc. cyclandelate, 200 mg.

18. Samples of Premo Pharmaceutical Laboratories, Inc. cyclandelate, 200 mg.

19. Samples of Premo Pharmaceutical Laboratories, Inc. cyclandelate, 400 mg.

20. Bottle of Rugby Laboratories, Inc. cyclandelate, 200 mg.

21. Bottle of Rugby Laboratories, Inc. cyclandelate, 400 mg.

22. Bottle of Darby cyclandelate, 200 mg.

23. Bottle of Darby cyclandelate, 400 mg.

24. Bottle of Sherry cyclandelate, 200 mg.

25. Bottle of Sherry cyclandelate, 400 mg.

26. Specimens of Premo price lists and product sheets.

27. Specimens of Inwood price lists and product sheets.

28. Catalogues of Sherry, Darby and Rugby.

29. Bottle of CYDEL cyclandelate, 200 mg.

30. Bottle of CYCLANFOR cyclandelate, 400 mg.

31. Bottle of CYCLANFOR cyclandelate, 200 mg.

32. Prescription Bottles and prescriptions:

    a. Dispensed prescription bottle, Lowitt Labs, Inc., "1-25-78".

    b. Dispensed prescription bottle, Tylertown Drug Store "Cyclospasmol 200 mg 2-16-78".

c. Dispensed prescription bottle, Pickwich Pharmacy "Cyclospasmol 200 mg. 3-15-78".

d. Dispensed prescription bottle, Pickwick Pharmacy "Cyclospasmol 400 mg. 3-22-78".

e. Dispensed prescription bottle, Pickwick Pharmacy "Cyclospasmol 200 mg. 3-15-78".

f. Dispensed prescription bottle, Merill Pharmacy "Cyclospasmol 200 mg. 3-22-78".

g. Dispensed prescription bottle, Civic Drug Center "Cyclospasmol 400 mg. 3-27-78".

h. Dispensed prescription bottle, Carylsle pharmacy "Cyclospasmol 400 mg. 4-24-78".

i. Dispensed prescription bottle, Sentry Drugs, Taylor, Michigan "Cyclospasmol 400 mg. 4-24-78".

j. Dispensed prescription bottle, Sentry Drugs, Southfield, Michigan "Cyclospasmol 400 mg. 4-25-78".

k. Dispensed prescription bottle, Carlysle Pharmacy "Cyclospasmol 200 mg. 4-27-78".

l. Dispensed prescription bottle, Sentry Drugs, Taylor, Michigan "Cyclospasmol 200 mg. 4-27-78".

m. Dispensed prescription bottle, Sentry Drugs, Southfield, Michigan "Cyclospasmol 200 mg. 4-27-78".

34. Bottle containing capsules for use in physicians' interview. (Reserve right to object).

35. Bottles containing capsules for use in patient interview re 200 mg. cyclandelate. (Reserve right to object).

36. Bottles containing capsules for use in patient interview re 400 mg. cyclandelate. (Reserve right to object).

37. Specimen questionnaire for physicians. (Reserve right to object).

38. Specimen questionnaire for patients. (Reserve right to object.).

39. Instructions to interviewers. (Reserve right to object).

40. Analysis of survey results, and back-up material. (Reserve right to object).

41. Completed questionnaires, with the names of patients and physicians masked. (Reserve right to object).

42. List of physicians who are believed to prescribe CYCLOSPASMOL. (Reserve right to object).

43. Instructions to Ives detail men re identity of physicians and pharmacies. (Reserve right to object).

44. List of pharmacies in New York State that are believed to dispense both CYCLOSPASMOL and generic cyclandelate. (Reserve right to object).

45. Analysis of results of shopping in New York State. (Reserve right to object).

46. Map showing area covered by survey. (Reserve right to object).

47. Dispensed prescription bottles from the following pharmacies, with envelopes showing shoppers' records and containing receipts and copies of prescriptions: (Object unless foundation is laid).

Genaud Sidney Pharmacy (Gibson Chemical) Valley Stream, New York.
Middle Neck Pharmacy, Great Neck, New York.
Parkdale Pharmacy, Valley Stream, New York.
A & S Rx Center, Hempstead, New York.
Rosebank Pharmacy, Staten Island, New York.
Tri-Boro Pharmacy, Astoria, New York.
Health World Pharmacy, Flushing, New York.
Marder's (Ron-See Drugs) Laurelton, New York.
Pharmacy at Leisure Country, Ridge, New York.

Simelson's Square Pharmacy, Bronx, New York.
Miele Pharmacy, Brooklyn, New York.
Cur-Al Rx Center, Hempstead, New York.
Finast Supermarkets, Bronx, New York.
Rxcetera Drugs, Valley Stream, New York.
Genovese Rx, Shirely, New York.
Zive Pharmacy, Bronx, New York.
Drug Masters, Hempstead, New York.
Economy Drug, Williston Park, New York.
Gibson Chemist, Valley Stream, New York.
County Pharmacy, Brooklyn, New York.
Seaport Pharmacy, Port Jefferson, New York.
Vadala's Pharmacy, Highland, New York.
Rite Aid Pharmacy, Yonkers, New York.
Bronx Rx Center, Bronx, New York.
Anscott Rx, East Northport, New York.
Leff, Bronx, New York.
Nu-Era, Bronx, New York.
Genovese Drugs, Mt. Vernon, New York.
Martini's Northside Pharmacy, James Point, New York.
Leda Pharmacy, New York, New York.
Gilliar Drugs, Great Neck, New York
Birchwood Pharmacy, Bayside, New York.
Wading River Pharmacy, Wading River, New York.
Austin Drugs, Great Neck, New York.
Tick Tock Drugs, East Northport, New York
Nordale Rx, East North Port, New York.
Sloatsburg Pharmacy, Sloatsburg, New York.
Samone Pharmacy, Oyster Bay, New York.
Wykagyl Pharmacy, New Rochelle, New York.
Franconia Pharmacy, Flushing, New York.

Procita Pharmacy, West Babylon, New York.
Pound Ridge Pharmacy, Pound Ridge, New York.
The Medicine Shoppe, Northport, New York.
Grimaldi Pharmacy, Inc., Brooklyn, New York.
Long Island Prescription Center, Cedarhurst, New York.
Town Hall Pharmacy, Elmsford, New York.
Pathmark Drugs, Copaigue, New York.
Drug Mart, Bellmore, New York.
Linden Park Pharmacy, Howard Beach, New York.
Ace Pharmacy, Riverdale, New York.
Hunts Point Drug Co., Bronx, New York.
Ellvin Drugs, Hempstead, New York.
Steward Drugs, Bayside, New York.
Franhill Drugs, Hollis, New York.
Orso Drug Co., Inc., Valley Stream, New York.
Arkay, New York, New York.
Town Hall Pharmacy, Elmsford, New York.
CVS Pharmacy, Rochester, New York.
Rite Aid Pharmacy, Utica, New York.
Carl Drug Company, Auburn, New York.
Rite Aid Pharmacy, LeRoy, New York.
Oneida Square Pharmacy, Utica, New York.
Carls Drug Company, Oneonta, New York.
Loudon Pharmacy, Albany, New York.
Canton Drugs, Tonawanda, New York.
Winchell's Pharmacy, Greenwich, New York.
Webster Drugs, Bronx, New York.
Jax Leader Drugs, Rochester, New York.
Crone Supe-Rx Drugs Inc., Johnson City, New York.

Park Pharmacy, Johnson City, New York.
Wegmans Pharmacy, East Rochester, New York.
Rite Aid Pharmacy, Utica, New York.
Rite Aide Pharmacy, Syracuse, New York.
Bert A. Lies Pharmacy, Cheektowaga, New York.
Northside Apothecary, Rochester, New York.
Rite Aide Pharmacy, Utica, New York.
Beaver Pharmacy, Canisteo, New York.
Hargrave's Pharmacy, Fulton, New York.
MacFinn Drug Company, Saratoga Springs, N.Y.
Seth Drugs, Scotia, New York.
Luizzi Pharmacy, Inc., Endicott, New York.
The Parkleigh Pharmacy, Rochester, New York.
Fisk & Penning Pharmacy, Kenmore, New York.
K. Drugs, Tonawanda, New York.

48. Curricula vitae for plaintiff's expert witnesses.

49. Premo request for hearing concerning cyclandelate filed with FDA. (Objected to as irrelevant).

50. Physicians Desk Reference, 1977 and 1979 Editions.

51. Samples of the following prescription drugs in the same dosage form, but in different colors:

a. papaverine hydrochloride (a vasodilator).

b. amitriptyline hydrochloride (an anti-depressant).

c. chlordizaepoxide hydrochloride (tranquilizer).

52. Chart showing prescription drugs in the same dosage form, but in different colors. (Reserve right to object).

53. Specimens and labelling re change of colors of PHENERGAN product. (Object as irrelevant).

54. Records and specimens from Calvin Pharmacy. (Reserve right to object).

55. Specimen prescription bottles obtained from patients participating in survey interviews. (Object as being irrelevant and immaterial).

56. IMS material concerning frequency of prescribing of various drugs, including cyclandelate, specifically:

a. IMS American National Prescription Aduit Therapeutic Category Report October, 1979 pp. 204, 207, 315.

b. IMS American National Prescription Aduit Therapeutic Category Report December, 1978 pp. 197, 303, 199.

c. National Disease and Therapeutic Index pp. (1)-(7); (13), (14); January-December

1978, pp. 901, 905; p. 276; October, 1978-September, 1979 pp. 900, 907, 1281.

57. Publication showing names of most widely prescribed drugs.

58. Catalogues from other generic manufacturers or distributors.

B. Defendants' Exhibits:

1. Premo:

1. Curriculum Vitae of Dr. Stempel.

2. Bibliography of Dr. Stempel.

3. Part III, January 1979 New York State Pharmacy Boards. (Plaintiff reserves right to object).

4. Board with look-alike drugs. (Object as to relevancy).

5. Key to Exhibit 4.

6. Prescription for Cyclospasmol. (Reserves right to object).

7. Pharmacist's label of Cyclospasmol. (Reserves right to object).

8. Prescription for cyclandelate. (Reserves right to object).

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9. Pharmacist's label for cyclandelate. (Reserves right to object).

10. Premo's bottle of 200 mg. cyclandelate.

11. Premo's bottle of 400 mg. cyclandelate.

12. Curriculum Vitae of Dr. Bloom.

13. Apresoline 50 mg. — Ciba. (Reserves right to object).

14. Hydralazine 50 mg. — Lederle. (Reserves right to object).

15. Antivert 25 mg. — Roerig. (Reserves right to object).

16. Antivert 12.5 mg. — Roerig. (Reserves right to object).

17. Meclizine Hcl. 12.5 mg. — Lederle. (Reserves right to object).

18. Meclizine Hcl. 25 mg. — Lederle. (Reserves right to object).

19. *Physicians' Desk Reference.*

20. Schein catalog — Pre-Winter 1979.

21. Schein catalog - Winter 1979.

22. Current Premo catalog. (Reserves right to object).

23. a. Prescription for Cyclospasmol filled at East View Apothecary.*
    b. Receipt for Exhibit 23a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 23a.

24. a. Prescription for Cyclospasmol filled at Four Corners Pharmacy.
    b. Receipt for Exhibit 24a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 24a. (Objection).

25. a. Prescription for Cyclospasmol filled at Prescriptions Exclusive.
    b. Receipts for Exhibit 25a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 25a. (Objection).

26. a. Prescription for Cyclospasmol filled at Prescriptions Limited of Madison Avenue.
    b. Receipt for Exhibit 26a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 26a. (Objection).

27. a. Prescription for Cyclospasmol filled at Rite Aid Pharmacy.
    b. Receipt for Exhibit 27a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 27a. (Objection).

28. a. Prescription for Cyclospasmol filled at Barney's Prescriptions.

Plaintiff objects to all exhibits in 23 through 47 unless defendant Premo produces for inspection *all* prescriptions filled in the Chung shoppings.

b. Receipt for Exhibit 28a.
c. Cyclospasmol capsules filled in response to prescription for Exhibit 28a. (Objection).

29. a. Prescription for Cyclospasmol filled at Church Pharmacy.
b. Receipt for Exhibit 29a.
c. Cyclospasmol capsules filled in response to prescription of Exhibit 29a. (Objection).

30. a. Prescription for cyclospasmol filled at Dan's Grand Avenue Pharmacy.
b. Receipt for Exhibit 30a.
c. Cyclospasmol capsules filled in response to prescription of Exhibit 30a. (Objection).

31. a. Prescription for Cyclospasmol filled at Group Drug Service (Maiden Lane).
b. Receipt for Exhibit 31a.
c. Cyclospasmol capsules filled in response to prescription of Exhibit 31a. (Objection).

32. a. Prescription for Cyclospasmol filled at Sav-On Drug Store.
b. Receipt for Exhibit 32a.
c. Cyclospasmol capsules filled in response to prescription of Exhibit 32a. (Objection).

33. a. Prescription for Cyclospasmol filled at D & R Pharmacy, Inc.
b. Receipt for Exhibit 33a.
c. Cyclospasmol capsules filled in response to prescription of Exhibit 33a. (Objection).

34. a. Prescription for Cyclospasmol filled at Pathmark Pharmacy (Fulton St., Brooklyn).
    b. Receipt for Exhibit 34a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 34a. (Objection).

35. a. Prescription for Cyclospasmol filled at DJ Drug.
    b. Receipt for Exhibit 35a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 35a. (Objection).

36. a. Prescription for Cyclospasmol filled at Willner Drug Shop, Inc.
    b. Receipt for Exhibit 36a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 36a. (Objection).

37. a. Prescription for Cyclospasmol filled at Norwood Rexall Drugs.
    b. Receipt for Exhibit 37a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 37a. (Objection).

38. a. Prescription for Cyclospasmol filled at Group Drug Service (Beekman Street).
    b. Receipt for Exhibit 38a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 38a. (Objection).

39. a. Prescription for Cyclospasmol filled at Health Wise Pharmacy.
    b. Receipt for Exhibit 39a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 39a. (Objection).

40. a. Prescription for Cyclospasmol filled at Lipton Chemists Inc.
    b. Receipt for Exhibit 40a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 40a. (Objection).

41. a. Prescription for Cyclospasmol filled at Abraham & Straus Prescription Department.
    b. Receipt for Exhibit 41a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 41a. (Objection).

42. a. Prescription for Cyclospasmol filled at Bonus Drug Inc.
    b. Receipt for Exhibit 42a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 42a. (Objection).

43. a. Prescription for Cyclospasmol filled at Kings Pharmacy.
    b. Receipt for Exhibit 43a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 43a. (Objection).

44. a. Prescription for Cyclospasmol filled at Pathmark Pharmacy (880 Third Ave.)
    b. Receipt for Exhibit 44a.
    c. Cyclospasmol capsules filled in response to prescription of Exhibit 44a. (Objection).

45. a. Prescription for Cyclospasmol filled at Greenfield, The Chemist.

b. Receipt for Exhibit 45a.

c. Cyclospasmol capsules filled in response to prescription of Exhibit 45a.(Objection).

46. a. Prescription for Cyclospasmol filled at BJS Drugs, Inc.

b. Receipt for Exhibit 46a.

c. Cyclospasmol capsules filled in response to prescription of Exhibit 46a. (Objection).

47. a. Prescription for Cyclospasmol filled at Prescriptions Limited of Broadway.

b. Receipt for Exhibit 47a.

c. Cyclospasmol capsules filled in response to prescription of Exhibit 47a. (Objection).

48. Premo invoice to Generix Drug Sales Co. for 200 mg. cyclandelate capsules, dated 1/7/76.

49. Premo invoice to Valley Pharmaceutical & Vit. for 400 mg. cyclandelate capsules, dated 1/7/76.

50. Curriculum Vitae of Dr. Sorensen.

51. Patient Pill Board.

2. Inwood:

1. Samples of Inwood's cyclandelate, 200 mg., bearing NDC imprint #258.

2. Samples of Inwood's cyclandelate, 400 mg., bearing NDC imprint #258.

3. Specimens of Inwood price lists and product sheets.

4. Various United States Veterans Administration specifications for various pharmaceutical products. (Objection without foundation).

5. United States Government Federal Standard for Capsules for Medicinal Purposes, dated January 7, 1977. (Objection without foundation and reserves other objection until the document has been produced).

6. Publication of the New York State Assembly's Office of Legislative Counsel entitled, "Are Generics Safe", dated June 23-24, 1978. (Objection without foundation and reserves other objection until the document has been produced and read).

7. Federal Register notices appearing in 44 F.R. 30436-37, 30443-30446 (May 28, 1979).

8. &
9. Samples of Inwood's cyclandelate, 200 m.g. & 400 m.g. bearing the "Inwood" name imprinted thereon.

10. Curriculum Vitae of Dr. Shafer

11. State of New Jersey Purchase Bureau Records 1976-77.

3. Sherry, Darby, Rugby and MD:

1. Curriculum Vitae of Dr. Taylor.

2. Curriculum Vitae of Dr. Shinbach.

3. Records of defendants Darby and Rugby as to when they began purchasing cyclandelate from manufacturers for re-sale to doctors, pharmacies and hospitals.

4. Records of defendants Darby and Rugby as to representations, guarantees and warranties made by companies which sold cyclandelate to said defendants. (Objection as to relevance).

5. Catalogues of various generic drug wholesalers. (Objection)

6. Examples of capsules to be used by Darby, Rugby and Sherry with the same Rugby imprinted thereon together with code number.

7. Records of defendants Darby and Rugby showing breakdown of sales of cyclandelate to doctors, to pharmacies and to others.

8. Letter by Dr. Taylor printed in the New England Journal of Medicine, May 18, 1978 issue.

IV. Witnesses:

The names and addresses of the witnesses, together with a brief narrative of their expected testimony, are as follows:

A. Plaintiff's Witnesses:

1. Herbert Lowenkrohn
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Lowenkrohn will testify about the general nature of the Ives business and about CYCLOSPASMOL cyclandelate including extent of sales, type and extent of promotion, intended use of the product, categories of patients likely to use the product, methods of distribution, availability of colored capsules on the open market, and harm to Ives arising from the conduct of the defendants.

2. Alfred Ling, M.D., Ph. D.
Ives Laboratories
685 Third Avenue
New York, New York

Dr. Ling will testify about the extent, nature and cost of the clinical investigations on cyclandelate done by Ives for submission to the FDA.

3. Fred Bovoso
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Bovoso will testify about the detailing of CYCLOSPASMOL cyclandelate to physicians, about the availability on the market of the same drugs in the same dosage form but in different colors, and about the gathering by Ives personnel of information concerning physicians prescribing and pharmacies dispensing CYCLOSPASMOL cyclandelate.

4. David Getson, M.D.
Maine Medical Center

Department of Emergency Medicine
Portland, Maine 04104

Dr. Getson will testify about procedures followed in the emergency room of a hospital in the case of drug overdose.

5. Heinz E. Lehmann, M.D.
Royal Victoria Hospital
Allan Memorial Institute
Pearl and Pine Streets
Montreal, Canada

Dr. Lehmann is a psychiatrist who will testify about his experience with patient receptivity to changes in the colors of drugs products dispensed to them.

6. Eric W. Fine, M.D.
1315 Walnut Street
Philadelphia, Pennsylvania 19107

Dr. Fine is a physician who will testify about his experience with patient receptivity to changes in the colors of drug products dispensed to them.

7. Vincent C. Desiderio, M.D.
2116 Chestnut Street
Philadelphia, Pennsylvania

Dr. Desiderio is a physician who will testify about his experience with patient receptivity to changes in the colors of products dispensed to them, and as to his practice in dispensing various colors of drug products.

8. Herbert Price
Director of Pharmacy
Nassau County Medical Center
East Meadow, New York 11554

Mr. Price will testify concerning his experience in purchasing and dispensing prescription drug products in the same dosage form, but in different colors.

9. Brendan Lawler
Trottas West Street Pharmacy, Inc.
15 Halstead Avenue
Harrison, New York 10528

Mr. Lawler will testify concerning pharmacy practice and his experience in purchasing and dispensing prescription drug products in the same dosage form, but in different colors.

10. Paul J. Smith
Wyeth Laboratories
Philadelphia, Pennsylvania

Mr. Smith will testify about the experience of Wyeth Laboratories (a division of American Home Products) when it has changed the color of a prescription drug product.

11. John M. Kashickey
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Kashickey will testify about the practices followed by various governmental agencies when purchasing or seeking bids concerning drug products.

12. Dr. Benjamin Lipstein
Lipstein, Assael & Associates
333 East 57th Street
New York, New York

Dr. Lipstein will testify concerning the design of, and will analyze the results of the survey of physicians and patients. He will also testify concerning the results of shoppings done at various pharmacies in the State of New York, and about the way in which said pharmacies were selected.

13. Dr. Harry Heller
Harry Heller Research Corp.
358 Main Street
Port Washington, New York

14. Doris Lesansky
Harry Heller Research Corp.
358 Main Street
Port Washington, New York

15. Janet Bernstein
Harry Heller Research Corp.
358 Main Street
Port Washington, New York

16. Joan Milnamow
Harry Heller Research Corp.

358 Main Street
Port Washington, New York

Dr. Heller, Mrs. Lesansky, Mrs. Bernstein and Mrs. Milnamow will testify about the execution of the physician and patient surveys. In addition, plaintiff will call one field supervisor, and one interviewer, both from Syracuse, New York — Eleanor Caracca and Elise Lavalle.

17. Dr. Stephen Chappell
(or R. Lars Olson)
IMS America Ltd.
Ambler, Pennsylvania

The IMS witness will testify concerning his company's statistical back-up as to the identity of the most widely prescribed drugs and the number of physicians prescribing CYCLOSPASMOL cyclandelate in the United States.

18. Seymour Adler
2300 Olinville Avenue
New York, New York

19. Carl Kittelberger
c/o Seymour Adler

20. Sander Eisenberg
c/o Seymour Adler

21. Alfonso Paske
Lakeview Estates
918 Reed Canal Road
Daytona Beach, Florida

The above-identified witnesses, and Mr. Adler, will testify that they took prescriptions into pharmacies in New York State, had them filled, and then turned the bottles containing the prescriptions, along with a record concerning the pharmacy shop, to Dr. Lipstein or plaintiff's law firm in the same container as when purchased. Mr. Paske will testify by telephone communication if necessary.

22. Frank Whalen
Ives Laboratories
Eureka, Illinois

23. William Hastings
Ives Laboratories
Syracuse, New York

24. Kay Brady
Ives Laboratories
685 Third Avenue
New York, New York

Mr. Whalen, Mr. Hastings and Miss Brady obtained packages of generic cyclandelate labelled CYCLOSPASMOL from patients who participated in the survey interview.

25. Helen Gaucci
Ives Laboratories
685 Third Avenue
New York, New York

Miss Gaucci will testify concerning the transfer of physicians' names, addresses and telephone numbers

from material furnished by detail men into computerized form. She will testify only if no stipulation can be arrived at concerning this matter.

B. Defendants Witnesses:

1. Premo:

As Presently advised, defendant Premo Pharmaceutical Laboratories, Inc. intends to call the following witnesses at trial.

1. Dr. Edward Stempel
Associate Dean
Schwartz College of Pharmacy
75 DeKalb Avenue
Brooklyn, New York 11201

Dr. Stempel is an expert in the field of pharmacy and pharmaceutical practice and will testify as to the facts contained in the affidavit he submitted herein, the manner in which certain aspects of training of pharmacy students is conducted, and pharmaceutical dispensing practices.

2. Donna Gringauz
St. John's Episcopal Hospital
327 Beach 19th Street
Far Rockaway, New York 11691

Ms. Gringauz will testify about the disadvantages of dispensing generic drug which are not look-alike of branded drugs and the advantages of standarization.

3. Martin Sperber
Vice President
Henry Schein, Inc.
5 Harbor Park Drive
Port Washington, New York 11050

Mr. Sperber will testify and give opinions as to the need for comparative advertising in selling generic drugs and the desirability of having generic look-alikes.

4. Dr. Jerry Bloom
Brookdale Hospital Medical Center
Linden Boulevard at Brookdale Plaza
Brooklyn, New York 11212

Dr. Bloom is an internist and will testify as to the desirability of having generic look-alikes and the manner in which patients use the appearance of drugs to identify their daily regimen of drug intake.

5. Mr. Douglas Chung
344 East 17th Street
Brooklyn, New York 11226

Mr. Chung is a registered pharmacist and conducted the shoppings in the New York area to ascertain whether or not illegal substitution occurs with respect to prescriptions calling for Cyclospasmol. He will also testify about his experience in identifying drugs on the basis of size, shape, and color.

6. Dr. Robert C. Sorensen
Robert C. Sorensen and Associates, Inc.

210 East 72nd Street
New York, New York 10021

Dr. Sorensen is a survey and market research expert who will testify and give opinions regarding the survey conducted by Ives.

7. John Blackman, Vice President
Premo Pharmaceutical Laboratories, Inc.
111 Leuning Street
South Hackensack, New Jersey

Mr. Blackman will testify as to Premo selling cyclandelate and the manner in which it is offered for sale.

2. Inwood

1. Seymour Field
Inwood Laboratories, Inc.
300 Prospect Street
Inwood, New York

Mr. Field will testify about the marketing practice of Inwood and the general practice of selling generic drugs with the same appearance as their brand name counterparts.

2. Dr. Nathaniel Shafer
10 East 85th Street
New York, New York 10028

Dr. Shafer is a physician who will testify about his experience with generic drugs in general, and

cyclandelate specifically and his opinions with respect to the importance of marketing generic drug products in the same color as their brandname counterparts.

3. Lee Kolodny
Director of Pharmacy
Parsons Hospital
35th Avenue and Parsons Blvd.
Flushing, New York 11354

Mr. Kolodny will testify as to his experience concerning patient anxiety and nurse confusion regarding the dispensing of drugs which are a different size, shape and color than the drug previously dispensed. He will also testify as to the Pharmacy's purchasing policy of drug products including cyclandelate.

3. Sherry, Darby, Rugby and MD:

1. Joseph Ashkin
Officer and Director of Darby, Rugby and Sherry

Mr. Ashkin will testify to the general practice of selling generic drugs with the same appearance as their brand name counterparts; the use of brand names in conjunction with generic names in the catalogues of generic drug wholesale distributors; and the reasons for these common practices.

2. Kent D. Shinbach, M.D.
435 East 79th Street
New York, New York 10028

Dr. Shinbach is a psychiatrist who will testify about his experience and his opinions with respect to patient receptivity to changes in the appearance of prescription drug products dispensed to them and the value of uniformity in the appearance of equivalent drug dosage forms.

3. Judith M. Taylor, M.D.
125 Worth Street
New York, New York 10013

Dr. Taylor is a physician who will testify about her experience and her opinions with respect to patient receptivity to changes in the appearance of prescription drug products dispensed to them and the value of uniformity in the appearance of equivalent drug dosage forms.

4. Defendants Darby, Rugby, Sherry and M.D. reserve the right to present witnesses concerning the shopping and product identification surveys conducted by plaintiff, and said defendants will provide notice of such witnesses upon completion of discovery.

V. Depositions to Be Offered:

A. By Plaintiff:

1. Seymour Blackman, President of Premo.
2. Seymour Field, Vice President of Inwood.
3. Joseph Ashkin, President of Sherry, Darby and Rugby.
4. Edward Stempel.
5. Calvin Pharmacy.

6. Kent Shinbach, M.D.
7. Donna Gringauz
8. Jerry Bloom, M.D.
9. Doris Lesansky

B. By Defendants:

1. Premo:
   1. Seymour Blackman
   2. Seymour Field
   3. Joseph Ashkin
   4. Calvin Pharmacy
2. Inwood:
   1. Seymour Field

VI. Plaintiff's Statement of Legal and Factual Issues:

The legal issues in the case and those involving mixed questions of law and fact are as follows:

A. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to the CYCLOSPASMOL cyclandelate capsules sold by plaintiff constitute a false designation of origin and a false representation in violation of Section 43(a) of the Federal Trademark Act?

a. Has the appearance of the capsules acquired secondary meaning signifying origin in a single source?

b. Is the fact that the copying by defendants was intentional itself evidence of secondary meaning?

c. Can the copying be excused if defendants are able to prove that the appearance of the capsules may perform some incidental functions?

d. Is duplication of the color, size and shape of the capsules necessary in order for the defendants to compete in the sale of generic cyclandelate?

e. Can it reasonably be concluded that patients will refuse to take medication different in appearance from that previously taken?

f. Does the sale by defendants of capsules identical in color, size and shape to plaintiff's create a likelihood of confusion, mistake or deception?

g. Does the presence of markings on the capsules and the labelling on a prescription bottle which states the name of the manufacturer and/or distributor obviate the likelihood of confusion?

g. Does the fact that cyclandelate is dispensed by prescription only make irrelevant the fact that consumer patients may be confused?

B. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to the CYCLOSPASMOL cyclandelate capsules sold by plaintiff constitute common law trademark infringement and unfair competition under the laws of the State of New York?

a. Has generic cyclandelate been passed off by pharmacies as CYCLOSPASMOL cyclandelate?

b. Can the defendants be held liable for having placed in the stream of commerce products of an appearance that facilitates such passing off?

c. Did the defendants in their sales and promotional material also actively contribute to the aforesaid passing off?

C. Are the defendants liable as contributory infringers for infringement of plaintiff's trademark CYCLOSPASMOL by pharmacists labelling look-alike generic cyclandelate with the trademark CYCLOSPASMOL?

D. Was Sherry's trademark SPASMOL, when used to identify cyclandelate, an infringement of plaintiff's federally registered trademark CYCLOSPASMOL?

E. Is it an act of false representation under Section 43(a) of the Federal Trademark Act, and an act of unfair competition under the laws of the State of New York, for the defendants to assert that their cyclandelate products are equivalent to the prescription drug product sold by the plaintiff under the designation CYCLOSPASMOL when the defendants have done no clinical investigations to determine whether in fact their products are equivalent?

F. Have the defendants, by selling look-alike prescription drug capsules containing cyclandelate, diluted the distinctive quality inhering in the appearance of plaintiff's CYCLOSPASMOL capsules in violation of the anti-dilution statute of the State of New York, General Business Law §368(d)?

G. Is plaintiff entitled to a permanent injunction against duplication of the appearance of the capsules in which its CYCLOSPASMOL cyclandelate is sold, and to an award of damages and an accounting of defendants' profits?

H. Is plaintiff entitled to an award of reasonable attorneys' fees?

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VII. Joint Statement of Defendants Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., Sherry Pharmaceutical Co., Inc. and Premo Pharmaceutical Laboratories, Inc. As To The Legal and Factual Issues

A. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to Cyclospasmol cyclandelate capsules sold by plaintiff constitute a false designation of origin and a false representation in violation of Section 43(a) of the Federal Trademark Act?

B. Has plaintiff met its burden of proof that its capsules have acquired secondary meaning?

C. Does the copying of a functional aspect of a product establish secondary meaning?

D. Can there be secondary meaning to the users of the capsules in question in view of the fact that they do not select the product which is dispensed to them?

E. Does the sale of the prescription drug cyclandelate in capsules identical in color, size and shape to the Cyclospasmol cyclandelate capsules sold by plaintiff constitute common law trademark infringement and unfair competition under the laws of the State of New York?

F. If the appearance of the capsules is functional, do the defendants have the right to use that appearance in selling their capsules?

G. Can color be the subject of a perpetual monopoly or acquire secondary meaning?

H. Are the defendants liable as contributory infringers for infringement of plaintiff's trademark Cyclospasmol by pharmacists labelling look-alike generic cyclandelate with the trademark Cyclospasmol?

I. Has plaintiff met its burden of proof that it is an act of false representation under Section 43(a) of the Lanham Act and an act of unfair competition under the laws of the State of New York for the defendants to assert that their cyclandelate products are equivalent to the prescription drug product sold by plaintiff under the designation Cyclospasmol when the defendants' and plaintiff's products each contain the identical active ingredient in the same amount and plaintiff has no proof that the products lack clinical equivalency?

J. Has the plaintiff met its burden of proof under Section 368(d) of the General Business Law of the State of New York that defendants have diluted a distinctive quality in the appearance of its capsules?

K. If defendants are prohibited from selling their blue and blue-and-red cyclandelate capsules, would plaintiff be given a perpetual monopoly on cyclandelate beyond that to which it was entitled under the patent laws?

VIII. Damages:

Plaintiff submits that any determination as to the amount of damages, as to an accounting for profits, and as to an award of attorneys' fees should be made in a separate proceeding, after a determination as to the issue of liability has been made.

Dated: New York, New York

January, 1980

ACCEPTED AND AGREED TO:

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UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, MODIFICATION TO PRETRIAL ORDER, FILED FEBRUARY 20, 1980

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

MODIFICATION TO PRETRIAL ORDER

Paragraph 27 of the Pretrial Order is hereby modified so as to read as follows:

> "27. Premo, Inwood and MD are manufacturers that sell cyclandelate capsules principally to wholesalers, hospitals and retail pharmacies. Premo is a manufacturer that sells cyclandelate capsules principally to wholesalers and hospitals.

Dated: Brooklyn, New York
February 19, 1980

SO ORDERED:

s/ Eugene H. Nickerson
U.S.D.J.

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, JUDGMENT FILED APRIL 29, 1980

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DABRY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL COMPANY, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants.

JUDGMENT

This matter having come before the Court, Honorable Eugene H. Nickerson, District Judge, presiding, and the issues having been duly tried and a decision on the motion of Ives Laboratories, Inc. for an injunction against defendants' alleged unlawful acts of trademark infringement, unfair competition, and violation of §43(a) of the Lanham Act having been rendered in an opinion dated April 15, 1980.

Judgment

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

(a) defendant Sherry Pharmaceutical Co., Inc., its officers, agents and employees and persons acting with or for them, be and hereby are permanently enjoined from directly or indirectly using as a trademark or trade name or as a component thereof the word CYCLOSPASMOL or any name, mark or word confusingly similar thereto or colorably imitative thereof, including but not limited to SPASMOL in connection with the sale of drug products, including the drug of the generic name of "cyclandelate" and from printing, publishing, distributing, displaying, offering for sale or advertising or in any other way using for the purposes of selling or advertising cyclandelate the word SPASMOL or any colorable imitation thereof, whether alone or together with other terms or designs; and

(b) all other counts of the complaint herein be and the same are hereby dismissed.

Dated: Brooklyn, New York
April 28, 1980

s/ Eugene H. Nickerson
U.S.D.J.

EXCERPTS FROM REPORTER'S TRANSCRIPT OF TRIAL PROCEEDINGS DATED JANUARY 21-30, 1980

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

Civil Action No. 78 C 372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff,

v.

DARBY DRUG CO., INC., et al.,

Defendants.

Pursuant to Supreme Court Rule 30.5, the page of the official transcript where the testimony is found appears in brackets. For the convenience of the Court, the name of the witness testifying appears at the initial instance where such testimony is set forth. It should also be noted that the official transcript is numbered as follows:

Trial Testimony on:

Jan. 21, 1980 — pp. 1a-126a;

Jan. 22, 1980 — pp. 1B-115B;

Jan. 23-30, 1980 — pp. 1-995.

* * *

Excerpts of Trial Proceedings

[Lowenkron, Tr. 18a] Q. What is Ives' business? A. They research, manufacture, and bring to the market and sale of pharmaceutical specialties.

Q. What do you mean by, "pharmaceutical specialities"? A. Chemical substances which have therapeutic effects that are used in the treatment of diseases.

Q. Approximately how many major drugs is Ives now distributing? A. About five.

Q Is cyclospasmol one of them? A. Yes, it is.

Q. What is the therapeutic indications for Cyclospasmol? A. It is a peripheral cerebral vasodilator.

Q. For us laymen, what does that mean? A. It opens the blood vessels to permit it more flow of blood.

Q. How many dosage strengths is Cyclospasmol sold in? [Tr. 19a] A. Three.

Q. What are they? A. One hundred milligram, two hundred milligram, and four hundred milligram.

Q. How long has Ives been selling the two hundred milligram capsule? A. Since '62.

Q. What color is that? A. Blue.

Q. Has it always been blue? A. Yes.

Q. How long has Ives been selling the four hundred milligram capsule? A. Since 1975.

Q. What color is that capsule? A. Blue and red.

Q. Has it always been blue and red? A. Yes.

Q. Do the Ives capsules have any imprint on them? A. Yes.

Q. What is the imprint on a blue, for example? A. The name, "Ives" in script and the NDC number.

[Tr. 20a] Q. On the four hundred milligram capsule? A. The same.

Q. Has that always been true, sir? A. Yes.

Q. Did you participate at all in the decision by Ives to select blue as the color of the capsule for the two hundred milligram? A. Yes, I was a member of the group that did the selection.

Q. Could you describe for the Court the circumstances which led to that selection? A. Well, we wanted to select a color that was distinctive and had some application to our company colors which were blue.

Q. You, however, — do you not at Ives sell capsules in colors other than blue? A. Yes.

Q. Why was that a factor in connection with the Cyclospasmol capsule? A. It was the first major product that we brought to the market and thus afforded us an opportunity to give it a distinctive color reminiscent of our company color.

Excerpts of Trial Proceedings

Q. Did you participate in the decision to select blue and red? [Tr. 21a] A. Yes, I did.

Q. What were the reasons, if any, for selecting that particular color combination? A. Well, we wanted to retain the blue for continued identification as a Cyclospasmol product and another color red to distinguish it from the all blue two hundred milligram capsule.

Q. Now, Mr. Lowenkron, I will show you what has been premarked Plaintiff's Exhibit 1 — after the defendants see what I am showing you.

(Exhibit shown to counsel.)

Q. (Continuing) I ask you to look at this exhibit and explain what the various elements in the exhibit are.

What is in the upper left hand corner? A. A white powder.

Q. Does it look to you like Cyclospasmol, cylandelate powder? A. Yes, it could be.

Q. What is the middle bin of the top of that exhibit? A. A clear, hard gelatin.

Q. Is cyclandelate ever sold in powder form? A. No.

[Tr. 22a] Q. Is the capsule one method for containing the powder so that it can be conveniently used by patients? A. Yes, it is.

Q. What is the capsule made of? A. Hard gelatin.

Q. Does that have any therapeutic value in connection with the drug? A. No, it does not.

Q. And would you explain what is in the upper right hand corner of the exhibit? A. One hundred milligram Cyclospasmol tablet.

Q. In other words, you chose tablet form for one of the dosages? A. Initially, yes.

Q. So a capsule is not absolutely necessary? A. No.

Q. And what are the bottom left and bottom middle bins; what do they contain? A. The bottom left contain blue capsules which are used in the manufacture of Cyclospasmol two hundred milligram capsules and the middle bin contains blue and red capsules which are used in the manufacture of Cyclospasmol four hundred milligram capsules.

Q. They're empty, right? [Tr. 23a] A. Yes.

Q. Do you manufacture your own capsules? A. No, we do not.

Q. Buy them from an outside organization? A. Yes.

* * *

[Tr. 24a] Q. I now hand you Plaintiff's Exhibit 3 and ask you if you can identify that for the Court. A. That is a gelatin capsule wheel.

Q. Who is it from? A. R.P. Scherer, one of the manufacturers of hard gelatin capsules.

Q. What is the purpose of that wheel? A. To aid in the selection of color combination for capsules.

Q. I also show you Plaintiff's Exhibit 4.

What is that? A. This is a similar device by Park Davis, another manufacturer of empty hard gelatin capsules and it serves the same purpose.

Q. Could you explain and display how it works?

THE COURT: You take a look and see what you want. It seems clear.

* * *

[Tr. 27a] Q. What is the basis of your knowledge about the pharmacy practice?

THE COURT: Do you need to go into that? Every now and then I buy a drug.

MS. DRISCOLL: Mr. Cobrin had indicated that he didn't think I had laid a sufficient foundation for the witness' knowledge.

THE COURT: Do you know anything about what pharmacists do?

THE WITNESS: I at one time worked in a pharmacy myself as a senior pharmacist and I have been in the industry

thirty-four years and I have spent many hours in pharmacies observing pharmacists in the process of doing their work.

Q. How has cyclospasmol been promoted? A. Through — of course our sales force — through direct detailing efforts to physicians and pharmacies and by means of print promotion in trade journals to the pharmacists and in medical journals to physicians and by direct mail.

Q. And how many people does Ives have employed to do detailing of a product such as Cyclospasmol? A. Approximately 230.

THE COURT: I recollect from what was in the papers, the promotion is primarily to the doctors; is that right?

THE WITNESS: Yes.

THE COURT: The pharmacist doesn't make a judgment as to which brand unless there is some generic?

THE WITNESS: The only time we advertise to the pharmacist if we come out with a new dosage or new size.

Q. Do the detail men also visit pharmacies? A. Yes.

Q. For what purpose? A. To inform him about the activities and to check stock.

THE COURT: You have to do your selling job to the doctor?

THE WITNESS: Yes, primarily.

Excerpts of Trial Proceedings

THE COURT: Really, entirely. Why else would you — a pharmacist can't overrule a doctor, can he?

THE WITNESS: No, he can't.

THE COURT: Why would you want — you'd want to tell him you have a new size?

[Tr. 29a] Why would you promote it — other than for —

THE WITNESS: And check stock, I said.

THE COURT: And check stock. All right.

Q. Do all pharmacies have to carry Cyclospasmol? A. Only if they get prescriptions.

Q. I now show you what has been marked Exhibit 11, and I will ask if you will identify the material in that collection. A. May I take a minute?

THE COURT: Yes.

I take it it is promotional material?

THE WITNESS: It is a collection and if I may look a second in sequence according to time - -

THE COURT: Yes.

All of that was put out by Ives?

THE WITNESS: Yes.

THE COURT: Okay.

THE WITNESS: Both for direct mail and distribution to physicians.

Q. Yes, — to whom was it distributed — I'm sorry — you anticipated my question.

Do you know approximately how many would be distributed for each of the promotional pieces? A. Depending upon how well the piece is received between 150 and 50,000.

[Tr. 30a] Q. I would like to refer to 11J.

Do you know how many times that particular piece was mailed out —

THE COURT: You mean, how many copies were mailed out or how many —

MS. DRISCOLL: I believe he said a mailing had approximately 50,000.

A. I recall this specific piece was one of the most successful ones I had and I think mailed about ten or twelve times.

Q. That is in color? A. Yes.

Q. Shows the color of the two hundred milligram capsule? A. Yes.

THE COURT: Somewhere between 500,000 to two million?

THE WITNESS: 500,000 and 600,000.

THE COURT: You said 50 to 150?

THE WITNESS: Yes, but this particular piece — counsel asked me about this particular piece and I said ten or twelve times. That would be 500,000 to 600,000.

Q. Would you now identify Exhibit 12, please? [Tr. 31a]
A. These are two versions of what we refer to as the basic information brochure therapeutic committees which contains the entire scientific and clinical literature of Cyclospasmol and contains a brochure that addresses itself specifically to nurses who are charged with the care of elderly patients receiving cyclospasmol.

Q. To what category of persons would Exhibit 12 be distributed?

MR. COBRIN: On something like this we have an objection and if you would sustain it, it would save some time. It seems to me there is a stipulation, at least as to Premo, that we entered the market in January of '76. If this literature was disseminated subsequent to the date when we entered the market, I don't see how they can rely on it. She'd have to show priority.

THE COURT: I don't see why not.

MR. COBRIN: The question is, they have to show that they have some property right before we entered the market. They can't develop their property right subsequent to our entry into the market.

Excerpts of Trial Proceedings

THE COURT: It may show strength. I think I will take it.

* * *

[Tr. 34a] MS. DRISCOLL: This is 11J which is one of the promotion pieces that went out. I believe that went out ten or eleven times. That shows the color of the two hundred milligram capsule.

(Exhibit shown to the Court.)

Q. Do you know approximately in what years 11J was distributed? A. I'd have to look on the back.

Q. Would it tell? A. The date is —

THE COURT: It doesn't say here. It says the patent number issued 8/67, this one.

THE WITNESS: It was during the year '67.

Q. Would you identify Exhibit 15, please? A. These are several versions of the Cyclospasmol physicians' file card which contains the prescription information on Cyclospasmol.

Q. Is that intended for daily use of the physicians or used during his practice? A. Well, many physicians maintain a book in which they keep these file cards for reference.

[Tr. 35a] THE COURT: May I see that, please?

(Exhibit shown to the Court.)

Excerpts of Trial Proceedings

THE COURT: They keep this in a file with their other drug things so they can pick it out?

THE WITNESS: It's prescription information.

THE COURT: So they'll see what they should prescribe?

THE WITNESS: Yes.

THE COURT: What do you call that, physician's file cards?

THE WITNESS: Yes, your Honor.

Q. And I now show you Exhibit 16, sir.

What is that? A. These are detailed folders which each of them highlighting one feature of the product which was used by our representatives and detailing physicians on Cyclospasmol.

Q. I now will show you together Exhibits 7 and 8 and ask if you will identify them to the Court. A. These are the physicians' samples on Cyclospasmol two hundred milligram and four hundred milligram which are distributed by our representatives to physicians in the course of detailing the product.

Q. They leave samples? [Tr. 36a] A. And they're mailed occasionally.

Q. Are you still sampling the blue 200 hundred milligram? A. Yes.

Q. The same quantities that you used to? A. Since the four hundred milligram has been marketed, the two hundred milligram was reduced commensurately.

Q. Sir, do you know the amount of yearly sales of Cyclospasmol in the two hundred milligram size? A. At the present time — can I refer to — I took notes.

THE COURT: Surely. You don't have them in your head.

MR. MARROW: May we see what he's referring to?

THE COURT: When he's finished you may see it.

It will refresh your recollection?

THE WITNESS: Yes.

A. In '69, two million five million three hundred and fifty-two thousand.

The four hundred milligram was four million eight hundred and thirty-four thousand.

Q. Could you tell us, if you do have a total, [Tr. 37a] since Mr. Cobrin is especially interested in before and after 1976, what were the sales of the blue two hundred milligram cyclospasmol prior to '76? A. I have a total from 1962 to 1979. It was eighty-nine million, approximately, and for the last ten years it was seventy-two million. So you take the differential between the time.

Q. Is it million unit dollars? A. Dollars.

Q. Has the sales of the two hundred milligram gone down in the last few years? A. Yes, they have.

Q. Can you elaborate on that? A. Well, of course, with the release of the four hundred milligram there was a reduction of sales in the two hundred milligram. If we go from dollars to units, there was a considerable reduction because at the same time there have been several price increases.

Q. Do you have a figure for the total sales of four hundred milligram blue-red cyclospasmol? A. Yes. Since the release in 1975 the total figure is seventeen million.

Q. Do you also know —

THE COURT: That is through '79?

[Tr. 38a] THE WITNESS: Yes.

Q. Sir, do you know the approximate amount of money that Ives has spent in connection with the promotion of Cyclospasmol? A. I would say in the last ten years, from between ten to twelve million dollars.

Q. And have you made any change in the way you promote or any special promotion efforts since the beginning of '76? A. No.

Q. Just the same as usual? A. Yes.

Q. Do you ever promote your product directly to patients? A. No.

Excerpts of Trial Proceedings

Q. Do you ever prepare material that can be distributed by physicians to patients? A. Yes, we refer to it as patient instruction material.

* * *

[Tr. 43a] Q. Is this product for acute or long term therapy? A. It is for chronic therapy.

Q. What does that mean? A. Long term therapy, it doesn't cure anything.

Q. You mean you keep taking it to alleviate a condition; is that what you're saying? A. To either alleviate or prevent further deterioration.

Q. Do you know what the — if a patient was, for example, taking two hundred milligram Cyclospasmol, do you know what the average number of capsules that he'd have to take per day would be? A. Four to eight.

Q. What about the four hundred milligram? A. Two to four.

Q. Can you describe if such a thing exists the category of patients who are more likely to be taking Cyclospasmol? A. They would be in the upper age groups.

* * *

[Tr. 45a] Q. Why is it not accurate? A. Because we haven't changed — we haven't changed the thrust of our advertising.

Excerpts of Trial Proceedings

THE COURT: In other words, even before other folks came with vasodilators, you had the same kind of advertising — in other words, it wasn't a comparison type thing?

THE WITNESS: No, it wasn't.

THE COURT: Okay.

Q. Are there other vasodilators on the market? A. Yes, there are.

Q. What are some of them? A. Vasodilin, Arlidin, Pavabid, Cerespan, Roniacol, to name a few.

Q. Are they cyclandelate or another form? A. They're different chemical entities.

Q. Are you the leading vasodilator on the market? A. No.

* * *

[Tr. 52a] A. One of your tablets is blue, but in coloring tablets, you have a different situation. I am not a technical man, but in order to color an uncolored tablet you have a problem, especially if you have four different ones.

Q. Why are all the dosage forms of Isordil different colors, why didn't you keep several dosage forms — A. To distinguish them from each other. They're the same size.

Q. Is that the same reason that the four hundred milligram capsule of Cyclospasmol is a different color from the two

hundred milligram capsule? A. As I testified before, we retained the blue and then we changed one segment of the capsule.

* * *

[Tr. 62a] Q. Many patients are given starter samples of Cyclospasmol by physicians? A. Yes.

Q. And they are provided by Ives, right? A. Yes.

Q. After the starter sample is given, the patient fills the prescription or refills the precription [sic] at a pharmacy, right? A. He has it refilled, yes.

* * *

Q. In the case of Cyclospasmol the patient [Tr. 63a] becomes familiar with the color because the treatment and management of peripheral vasodilator disorders require continuous treatment, right? A. Yes.

Q. This extended exposure leaves the patient with a strong visual picture of the appearance of the product he is taking, right? A. Yes, I believe you're quoting from my —

Q. Affidavit? A. Affidavit.

Q. And the patient relies on the appearance of the product to assure himself that he's receiving a proper medication? A. Yes.

* * *

Excerpts of Trial Proceedings

Q. During your direct testimony you referred to Exhibits 17A, B and C as documents given to a physician to be given to his patient giving the medication? [Tr. 64a] A. You'd have to show it to me. Yes.

Q. Can you show me where on this literature, Plaintiff's Exhibit 17A, B and C reference is made to the color of the medication? A. There is no reference made to any medication. It is not only custom, but a physician would not use any of these materials if there was a reference to any drug.

Q. The patient is never given any literature which contains a reference to the color of the drug; is that correct? A. No that is correct.

Q. The two hundred milligram capsule of Ives, that is the name Ives imprinted on it? A. Yes.

Q. Isn't it on the capsule so that somebody will see the Ives name and identify it as an Ives capsule? A. It depends on the circumstances under which an individual looks at the capsule.

THE COURT: What do you put it on for?

THE WITNESS: It is together with the NDC number to identify the capsule in case a prescription is question.

* * *

[Tr. 67a] Q. There is no literature that goes to the public which makes a reference to your drugs by color; is that correct? A. We are not allowed to distribute literature to the consuming public.

Excerpts of Trial Proceedings

Q. Would you answer my question, am I correct or incorrect? A. You're correct, obviously.

Q. Okay.

Now, you say you detail your Cyclospasmol product; is that correct? A. Yes, it is.

Q. And that is an expense to Ives, is it not? A. Yes, it is.

Q. And that expense to Ives is included in the cost of the drug when you sell it to your customers; is that not correct? A. Yes, it is.

Q. And generic drug companies don't detail their products, do they? A. No, they don't.

* * *

[Tr. 69a] Q. You said to your counsel that you were injured by — I guess you were referring to the defendants selling their cyclandelate product? A. Yes.

Q. You found out about it in 1976; is that not a fact? A. Yes.

Q. When did you feel you were injured, at what point in time? A. Well, this wasn't — it was a gradual process. We do review new and repeated prescriptions.

Q. Were you injured in '76 when you knew the defendants were out with their product? A. Yes, and the year after.

Excerpts of Trial Proceedings

Q. And you waited until '78 to bring the suit? A. It was gradual.

Q. I understand.

[Tr. 70a] Q. When did you feel that you were injured so severely that you had to bring the suit? A. Obviously prior to instituting the suit.

Q. So for the first two years you were not injured sufficiently enough; is that correct? A. It was a gradual process.

* * *

[Tr. 79a] Q. Now, you stated, I believe in connection with the questions of Mr. Marrow, that you believed your detail men would mention the generic word cyclandelate once in making a presentation to physicians at least once.

Would you explain why would that happen?

A. They're instructed at the end of the presentation when they leave the file card to make reference to the fact that the file card is for cyclandelate at least once, and the same thing is done in the literature.

Q. When are they given this instruction? A. Early during the training.

Q. You train detail men? A. Yes, we do.

Q. In training them, do you tell them what to say? A. Yes, we do.

Q. Also, in connection with Mr. Marrow's questioning and this may have been a misstatement or perhaps I heard it wrong.

I believe Mr. Marrow referred to the Cyclospasmol one hundred milligram capsule. In fact, is the one hundred milligram dosage form a capsule or is it some other form? A. It is a buff tablet.

* * *

[Bovoso, Tr. 85a] Q. Where do you work? A. New York is my home office, but I travel throughout the country.

Q. Can you tell us, for the record, what a medical sales representative does — is that the same as a detail man? A. Yes, it is. A sales representative basically calls upon doctors, hospitals, pharmacies and nursing homes detailing his product, making the doctor aware of them, leaving him samples and leaving him third-party material which will support the claims that are made by the company.

Q. And were you a medical sales representative in connection with the Cyclospasmol product? A. Yes, I was.

Q. And can you tell us approximately how many physicians you visited each week in connection with Cyclospasmol? A. In the normal week between 25 and 40 physicians.

Q. And how many pharmacies would you visit per week? A. Twelve to eighteen.

Q. Hospitals? A. Five to eight.

THE COURT: This is per —

Excerpts of Trial Proceedings

[Tr. 86a] THE WITNESS: Per week.

Q. How — over what years, Mr. Bovoso, did you make these visits in connection with the Cyclospasmol product as a medical sales representative? A. 1967 through 1974.

Q. And can you tell us, for example, what your visits to physicians in connection with Cyclospasmol would have entailed? A. Yes. It would be the detailing of the doctor about that particular product, leaving him third-party substantiation, leaving him broad sides, which are put out by the company which would point out the bulletined points made in the third-party literature.

Q. What do you mean by third-party literature? A. Studies that have been done by physicians that are not affiliated with Ives Laboratories.

Q. I will show you, Mr. Bovoso, what has been marked Plaintiff's Exhibit 14 and ask you if that is the kind of material to which you're referring. A. Yes, it is.

Q. And was that material used in connection with detailing Cyclospasmol? A. Yes, it was.

Q. Now, do you, over the course of the year [Tr. 87a] revisit some of the physicians that you already visited? A. Yes.

Q. As a sales representative? A. Yes.

Q. Now, about how often would you revisit any individual physicians over the year? A. According to the material that you have and earlier in the game we're talking about, we visited

the same physician between once every six and once every eight weeks. You should see the same physician roughly every six weeks.

Q. How long would your visit with the physician be in terms of time, each visit? A. With the actual physician it could vary from five minutes to half an hour, sitting in the office maybe another half-hour or so.

Q. Have you ever in your course of experience as a sales representative have any difficulty in getting appointments with physicians? A. Sure. Some physicians just see a salesman maybe once or twice a year. Some physicians probably not at all. There are few of them, but there are some.

Q. Now, I ask if you will look at Plaintiff's Exhibit 7 and 8, Mr. Bovoso, and tell me what, if anything, [Tr. 88a] a detail man would do with 7 and 8 —

* * *

THE COURT: Are you in charge of telling detail men what to do?

THE WITNESS: I was at one time, yes.

THE COURT: Answer it as of the time.

A. When you gave the doctor the product and told him as much as you could about the product and presented him with third-party material, you'd take out a sample and present him with it, making him aware of the product, how the dosages were to be prescribed as to the package insert, and leaving him all third-party material that we deemed appropriate at the time.

Q. Did you do this personally during your time as medical sales representative? A. I did it as a medical sales representative and district manager. I had the responsibility of training some of the people that came out of New York.

Q. Did you do that in connection with Cyclospasmol? A. Yes.

Q. What is the training school in New York to [Tr. 89a] which you refer? A. We have a training department in New York which trains our new representatives in some basic anatomy and physiology courses and some basic product knowledge.

Q. Do you yourself have any medical background? A. No.

Q. Do some sales representatives have some medical training? A. Yes, a number of them are science students when they were in high school — college — some may have been pre-med.

Q. How did you learn what should be said about Cyclospasmol when you were a sales representative? A. When I first came with Ives, the training is not as elaborate as it is today. I was taken by a district manager into a motel room for a week or ten days and he spent that time with myself and another individual, with a little book that they had which was used to train the man and the uses of our particular product and its competition.

Then you went into the field and were given a lot of things to read and put together. If you wanted to learn your trade you went home at night and did some reading.

Excerpts of Trial Proceedings

Q. Do you know whether there are any other [Tr. 90a] vasodilators on the market today other than the defendants' or generic cyclandelate in blue or blue/red capsules? A. None, to my knowledge.

Q. Now, would you please explain to the Court what you as a medical sales representative would have done when you visit pharmacies as opposed to physicians; what is your role? A. You'd go into a pharmacy, tell him that you were working in a particular area, especially if you're new or the area is new to you and we were a relatively small company and had large materials at the time and you'd be new in the area. You go into the pharmacy and tell him that you had been calling on the doctors, you'd detail him similarly to the way you'd detail the doctor, make sure he had your product in stock, if not attempt to secure an order through the company or a wholesaler.

Q. Could you describe your visits as a medical sales representative to hospitals and particularly in connection with Cyclospasmol? A. Well, you did the same thing at a hospital as you did in the doctor's office. You called on physicians and then the pharmacy.

Also you would like to make sure that the pharmacy had your product in stock in view of the fact that [Tr. 91a] you were detailing the doctors who were on the outside who may have a hospital practice who would be putting the patients into the hospital.

* * *

[Tr. 107a] Q. What did you do when you got to Ohio?

Excerpts of Trial Proceedings

* * *

THE WITNESS: I met with the salesmen and the district manager and asked him to fill me in as to what happened.

A. Then, what happened? A. We — I then went to a nursing home where he knew this drug was being distributed and I talked to the girls, told them that I was from New York, I was developing a unit dose package and since they found this was so nice would they mind giving me one.

A. Did they give you either or both Exhibits 26 and 27? A. They gave me quite a few.

[Tr. 108a] Q. Did they know you were removing it from the premises? A. I told them that I was talking it with me to develop something like that.

MS. DRISCOLL: I would like to call the Court's attention to 26, cyclandelate, Cyclosposmol.

THE COURT: Yes.

Q. Does the blister pack identified as Exhibit 26 contain Cyclospasmol? A. Well, we didn't think it did because there was no marking on it at all saying Ives.

Q. And Exhibit 27, which says Cyclospasmol, does that contain Cyclospasmol? A. No, for the same reason.

Q. It has no Ives name on it; is that correct? A. Correct.

Q. Did you pay for these samples? A. No.

Q. Did anyone ask you for payment? A. No.

* * *

[Tr. 120a] THE COURT: Going back to finding out about who had a propensity to substitute, if you find that your — the sales of your product are drying up or being reduced considerably, that indicates to you that one possibility is that he's substituting?

THE WITNESS: Yes.

THE COURT: That is all it indicates to you?

THE WITNESS: Yes.

THE COURT: Because there might be other possibilities that you mentioned?

THE WITNESS: Yes.

THE COURT: Then in order to find out whether, in fact, he's substituting or not, then you would go and shop them?

THE WITNESS: Only if this was initiated by the office. To do a shop on our own, I have never done that.

THE COURT: Is that a big deal to go send someone there and shop them?

THE WITNESS: You mean to make that decision on my own at the time?

Excerpts of Trial Proceedings

THE COURT: No, I mean to physically, is that very difficult?

THE WITNESS: It is very easy to do.

[Tr. 121a] THE COURT; Once you have the information that may alert you to the possibility that he is substituting, it is easy for you to send someone there to make a shopping and then you know for sure?

THE WITNESS: Yes.

* * *

[Tr. 8B] Q. I believe I asked you when detail men are taught how to detail there is a discussion about who the competition is, is that correct? A. Yes.

Q. Who do you regard as the competition? A. Other vasodilators.

Q. Who would they be? A. Arlidin Isoxsuprine, Papaverinehydrochloride.

If you would like the trade names I will give them to you.

A. Who manufactures those products? [Tr. 9B] A. Papaverinehydrochloride is manufactured by a number of people, USV, Marion; Arlidin is manufactured by USV; Isoxsuprine by Mead Johnson.

Dihydroergotimines are manufactured by Sandoz.

Q. These products are detailed in competition with your detail men? A. Yes, they are.

Q. When you teach a detail man about learning who the competition is, generally you stress your vasodilator is better or can do better than the competitors? A. Or does things differently, safer or better.

Any number of aspects.

* * *

[Tr. 10B] Q. You previously testified that detail men checked the stock of Cyclospasmol in pharmacies. A. That is one of their functions.

Q. In the pharmacy doesn't some pharmacist keep their stock by source so that it would be in one place? A. Yes.

Q. Is that a common practice? A. No more common than the other practice.

Q. Are detail people assigned a particular territory? A. Generally, yes.

Q. And do they visit all the doctors which are in that particular territory? A. They visit pre-selected doctors.

Q. How are those doctors pre-selected? A. You only have a limited number of hours in a day and limited number of time to do any particular job.

Excerpts of Trial Proceedings

[Tr. 11B] They have to take those particular doctors that they can establish a rapport with or in a specialty that uses those particular items.

If you are selling vasodilators you wouldn't see an Obgyn.

Q. They visit doctors regardless of whether they have purchased Cyclospasmol or not? A. Yes.

* * *

[Fine, Tr. 33B] Q. Have there been any occasions in your experience, sir, in which you have prescribed the same drug in the same dosage form to the same patient but in a different color? A. Yes, there have been occasions.

Q. Do you know for a fact specifically? A. Yes, I do.

Q. And can you tell the court some specific instances when this happened? A. Well, I know of a number of specific instances where for example I changed one patient's antidepressant medication from a drug called Sinequan to another drug called Adapin, which in fact is the same compound, Doxepin hydrochloride.

Q. You say this happened with one patient. Was it only one, sir? A. It happened with several patients.

In fact, it has happened with seven patients that I know specifically of over the past 12 months, approximately.

Q. How do you happen to know this specifically? A. I know it because I have looked at the medication sheets of patients that I have seen in the [Tr. 34B] clinic over the last year.

Excerpts of Trial Proceedings

* * *

[Tr. 35B] Q. Dr. Fine, I ask you if on page 423 there is a photograph of the Sinequan capsule to which you just referred. A. Yes, it's right here.

Q. Shows the color, does it not? A. Yes.

Q. Now, I refer you to page 422 and ask if the Adapin capsule is shown in color on page 422. A. Adapin is right here.

* * *

Q. I ask Dr. Fine if you would show the court which entries you referred to so the court can see the color differences. [Tr. 36B] A. It is a variety of colors depending on dosage.

In fact, it is the 25 and 50 milligram which I believe I prescribed.

* * *

Q. Has this happened, in your experience, this change of color in connection with any other drugs that you know of? [Tr. 37B] A. Well, I know for a fact that I have prescribed Librium, which is a very common minor tranquilizer. There have been several occasions where patients have in fact come back with their medication for the next appointment and had different color capsules because the Librium had been dispensed as chlordiazepoxide, which has different colors.

Q. What color is Librium? A. Ten miligram is a black and green capsule.

Excerpts of Trial Proceedings

Q. Is it your testimony that when the patient came back he had different color capsules? A. That's right.

Q. Did any of these patients exhibit to you any anxiety about the change in color? A. Not anxiety. They questioned why they were given a different pill or different capsule and were told obviously why it was.

Q. After you told them did they refuse to take it or express any anxiety? A. I have never experienced that.

Q. Did you ever notice any change in the therapeutic effect of the drug on such patients after the color change occurred? A. No, I didn't.

[Tr. 38B] Q. Is there a pharmacy in the hospital with which you are associated? A. Yes.

Q. Do you know the practice of that pharmacy insofar as the purchase of prescription drugs is concerned? A. Yes.

I believe they are on what they call a bid system where they buy the cheapest form of medication available and will in fact prescribe that medication even if it is written under a different proprietary name.

Q. Does your hospital pharmacy carry a lot of generics? A. Yes, it does.

Q. Do you know of any instances in which the pharmacy has dispensed generics in a color different from the name brand — branded product of the same kind of drug obviously? A. There are several examples of that.

Not necessarily only in generic. It might prescribe a cheaper form of the same drug, but a proprietary brand, whichever they find cheaper in the bidding process.

That has occurred within — when I have [Tr. 39B] written "Tofranil," Imipramine hydrochloride, which is the same drug but in a different shape and form. Same dosage.

Q. Is Tofranil in that instance the market leader? A. I don't know if it is the market leader. It is probably one of the first — was the first produced and it is the one that I have traditionally used over the years, the past ten, 12 years.

As the patent has become available to other companies, other companies have produced various forms.

Q. What is the therapeutic indication? A. It is a trycyclic antidepressant medication.

Q. Do you know of any difficulties in connection with your patients, for whom you prescribed Tofranil when another drug of a different color was prescribed in its place?

* * *

A. I know several patients have asked me after admission to the hospital, for example, because they were on the same medication that they were admitted with, but the actual form of the medication has appeared different [Tr. 40B] to them and several patients have asked me why am I getting different medication, and my answer is it is not different, it is the same and I have not noticed or been told of any ill effects from that.

Excerpts of Trial Proceedings

Q. Do you know any examples in connection with your hospital pharmacy other than in Imipramine? A. Librium is the classic example because it is a widely prescribed medicine and this is prescribed by the hospital pharmacy both in-patient and out-patient in the cheapest generic form available to the patient which is different in color from Librium.

Q. Are there any other products? A. I believe Amitriptyline, is also marketed or prescribed by the pharmacy or dispensed under a different name but I am not absolutely sure of its specific color, but I think it is different from Elavil which is a commonly-prescribed form.

* * *

Q. Do you know the source of the Amitriptylene dispensed in your hospital pharmacy? A. I am not absolutely sure of it, no, I am not.

* * *

[Tr. 42B] Q. Are the symptoms of arteriosclerosis, disorientation, difficulty in learning, difficulty in remembering things that happened recently and so forth? A. Those are symptoms.

Q. Are there any others? A. Confusion.

Deterioration of personal habits, personal care. Sometimes mood changes. It is complex and different in patients.

Q. Is cyclandelate prescribed? A. It is one of the medicines that is available, yes.

Excerpts of Trial Proceedings

[Tr. 43B] Q. Have you prescribed it for patients suffering that disease? A. Yes, I have.

Q. In some patients is Cyclospasmol contra-indicated if the arteries in the brain are so hardened that dilating blood vessels would drain blood away from the brain? A. That is still a controversial area.

Some argue it is the case and some others would argue there is no such thing as a steel syndrome.

My prescribings have been done in patients' relatively early stage.

I wouldn't be hesitant by prescribing it in patients more deteriorated but I would be doubtful of efficacy.

Q. Do you have any doubt of patients in early stages of cerebral arteriosclerosis? A. I think the evidence is controversial. I found it is better than placebo and therefore I have used it as adjunct to therapy, never in and of itself.

Q. Do patients suffering from the symptoms of arteriosclerosis sometimes take more than one drug — do they also have other diseases that they are suffering together with? [Tr. 44B] A. Yes.

Q. Is that fairly frequent? A. I would suggest that it is, yes.

* * *

Excerpts of Trial Proceedings

[Tr. 47B] Q. So if he were taking 200 milligram capsules he would take twice as many? A. Yes, if that was the way it was prescribed.

Q. If he confused his ergot alkaloid schedule with his cyclandelate and took that many ergotalkaloids capsules or tablets or whatever a day, would that cause a physical problem for the patient? A. Obviously it would be very unsafe.

Q. Would that also be true if he was taking a diuretic on the wrong schedule, might become dehydrated? A. Of course.

Q. Have you in your experience ever observed a patient who carries more than one medication in a pill box or a single container? A. Yes, I have.

Q. Do you consider this a healthy practice? A. No. I think it is a very bad practice.

Q. You have advised against it? A. I have advised patients to separate off dosages of drugs whenever they can, so they don't get confused.

Q. Is it possible that a patient with cerebral arteriosclerosis might forget the instruction because of the symptoms of the disease? A. It is possible.

[Tr. 48B] Q. In communicating with a patient, Doctor, do you ever refer to the color of a drug capsule for example — would you say take this blue capsule three time a day, take this red at meals and take the yellow before you go to bed? A. I try never to do that.

Q. Are you successful? A. Most of the time, I think.

Q. Does the patient ever refer to the color of the capsule when speaking to you, in asking you how many times should I take the blue capsule or things like that? A. That happens.

Q. Frequently? A. Depends what you mean by frequently. It certainly happens. It is not the most frequent thing to occur.

It does happen.

* * *

[Tr. 50B] Q. Now, when you have in the instances that you describe on direct changed the brand of the drug that was being prescribed and thereby changed the appearance of the drug, in those instances that you prescribed, you said that the patients asked you questions about it, is that correct? A. That's correct.

Q. And they were unsure that they were getting the proper medication, is that correct? A. They were taking what the medication was that they were getting.

THE COURT: I think you said some of them [Tr. 51B] said why was my medication changed.

THE WITNESS: That has been said too.

THE COURT: Yes.

Q. So isn't it safe to say that patients particularly on maintenance drugs such as cyclandelate or Cyclospasmol

become accustomed to the appearance of the capsules that they are taking on a daily basis? A. Patients do become accustomed to the tablets that they take daily, yes.

Q. In the patient's mind they sometimes rely upon this appearance to be sure that they are — to receive some assurance that they are taking the proper medication, is that correct? A. Sometimes they do.

* * *

[Tr. 53B] Q. You indicated that a number of patients carry a daily amount of medication in a pill box? A. Yes.

Q. Despite the fact that it might not be the best medical practice, many people do it to the contrary? A. They don't do it after seeing me if they retain their relationship with me. They divide their medicine but they continue to do it. When they see other doctors they do it.

When I see patients it is not infrequent when they will present a bottle with different types of medication.

Q. Despite your advice there are a significant number of patients who do mix medication, they comingle them, is that not correct? A. It would be against my advice for them to do so and I would check with them regularly.

Q. That is not my question.

Despite what you advised and your feelings about it, nevertheless there are a large number of patients or a certain

number that comingle? [Tr. 54B] A. There might be a number that would continue to do it.

Q. These patients who comingle, they rely on the sight of the medication to self-medicate? A. Some do; some don't.

Q. You spoke about Sinequan and Adapin. You said it is for anti-depressant, I believe. A. Yes.

Q. How long is a person on those medications? A. My practice is to recommend that they stay on either of those anti-depressants or any medication like that for a minimum of six months and they are reviewed on a regular basis and most patients with just enough depression require that for the better part of 12 months.

Q. Ever take it for life? A. Some people have taken it for ten, plus years and presumably will continue.

* * *

[Tr. 56B] Q. Do you believe if you have a patient who is a highly-confused state and doesn't speak English, that if you try to explain to him a certain medical situation and there will be a problem in understanding and accepting it? A. If a patient is confused, yes.

* * *

Q. Are you aware of a placebo effect in patients when they take medication? [Tr. 57B] A. Yes.

Q. Could you explain what that is? A. It is usually beneficial but sometimes not. The effect a patient has from a guard which is guarded from no chemical action, a chalk substitute, for example.

THE COURT: A sugar pill?

THE WITNESS: Or a sugar pill.

Q. But the patient believes he is benefitting by it, is that correct? A. That's right.

Q. And if the patient is then given a different drug is it possible that the placebo effect will be introduced at that point? A. I'm sorry, could you rephrase that?

Q. When the patient relies on that drug and that gives him a placebo effect — A. Yes.

Q. — now, an instance where a different drug is given, is it possible that the placebo effect would be interfered with? A. It is possible.

THE COURT: It would depend upon what you told him.

THE WITNESS: That's right.

[Tr. 58B] THE COURT: You might say this is a bigger and better — you wouldn't use the word placebo — a bigger and better drug, even though it was a placebo?

THE WITNESS: Exactly.

Q. Do you prescribe generically? A. Sometimes I do and sometimes I don't which is not a good practice of mine.

I have adopted American prescribing practices.

When I was trained I was always trained to prescribe generically and I tend to do what my colleagues do.

THE COURT: Why?

THE WITNESS: It is a poor practice.

THE COURT: What would be a good practice?

THE WITNESS: I think basic good practice would be to use a generic as a prescribing practice.

It induces a conformity and in terms of academic medicine, medical students would be more familiar with the basic molecule rather than a proprietary brand which might mean anything.

The reason I don't do it, because drugs have been marketed by drug companies under proprietary brands that have been advertised and those are the drugs that have led in the field [Tr. 59B] and been prescribed.

Tofranil would be an example which I have almost always prescribed as Tofranil because that is the name that everyone uses for it.

If I had my choice I would use generics. When I teach medical students I almost always do.

* * *

Excerpts of Trial Proceedings

[McCandless, Tr. 85B] Q. Can you describe the steps taken to develop a new drug for marketing in the United States?

* * *

A. Our first step is the actual chemical synthesis of the drug.

From there it goes to the pharmacology lab and they do what they call a profile and this is a battery of about ten tests to see if the drug has any activity.

If it does then they do more sophisticated animal testing.

We also do metabolism studies —

* * *

A. The toxicity of course is most important. Before the drug is actually put into any humans, there [Tr. 86B] there is usually a three-month — acute toxicity they call it. They do other toxicity studies.

They do — they put the drug into — usually mice, rats and rabbits, sometimes guinea pigs to get this profile.

THE COURT: Is this done before — this was done before you first started marketing Cyclospasmol, is this what you are talking about?

THE WITNESS: Those are the steps required for marketing a compound in the United States.

With the Cyclospasmol that was developed in Europe and some of these steps might have been missing.

Excerpts of Trial Proceedings

* * *

[Tr. 91B] Q. Is Cyclospasmol a Paragraph 14 drug? A. Yes.

Q. Would you describe for the court what a paragraph-14 drug is? A. This was -- paragraph 14, so-called, because the actual paragraph 14 of Judge Bryant's order which exempted certain classes of drugs from — exempted certain classes of drugs from being removed from the market while clinical testing was ongoing.

Q. And do you know, sir, if within the last year during 1979 the Food & Drug Adminsitration [sic] published a notice relating to specifially those paragraph drugs that are peripheral vaso-dilators? A. Yes, that was in May of '79.

Q. Did the notice include cyclandelate? A. Yes.

Q. Did it include all other periphera! vaso-dilators as well? A. Yes.

Q. Has Ives filed a request for hearing with the FDA in connection with that notice? A. Yes.

* * *

[Tr. 92B] Q. What is the subject of the notice? A. It is revoking the exemption clause that was given to us for continuing the clinical investigation while the product was being marketed.

One notice revoked this and the other notice stipulated a time frame to remove the product from the market or request a hearing.

Q. And in connection with that notice, has Ives submitted further information to the FDA concerning the effect of the drug? A. Yes. We did in July of '79.

Q. And is there a date set down for a hearing on this matter? A. Not to my knowledge.

* * *

[Tr. 102B] Q. Who are the other companies that have filed requests for a hearing on this issue? A. The National Association of Pharmaceutical Manufacturers filed in behalf of a few of their members, and also I learned this morning that Premo Laboratories has filed.

MS. DRISCOLL: Your Honor, we have a stipulation that among the members of the association for whom requests for hearing have been filed Inwood, the defendant, is one of them.

Q. Do you know, Mr. McClandess, whether the paragraph fourteen exemption was granted to Cyclospasmol because of a medical need for the drug? A. Yes, it was. It was granted to about at least twenty therapeutic classes of drugs. They felt there was a medical need to keep it on the market during this time while it was being tested.

* * *

[Pangburn, Tr. 9] Q. Where is Persse's Prescription Shop? A. It's in Savannah, Georgia.

Q. And approximately when did you purchase Exhibit 19 from this pharmacy? A. To the best of my recollection, it was in January of 1978.

Q. Were you instructed to do so by anyone? A. Yes, sir.

Q. Who was that? A. Mr. Baron. Let me clarify that. That came from my district manager, who was told was on the —

THE COURT: All right.

A. (Continues) Under the direction of Mr. Baron.

Q. Now, Mr. Pangburn, did you obtain Exhibit 19 pursuant to a prescription? A. Yes, sir.

Q. And what did you do with the bottle in Exhibit 19 when you received it? A. I sent the bottles to my district manager.

* * *

[Tr. 11] Q. Mr. Pangburn, have you ever seen Exhibit 19 before? A. Yes, sir.

Q. Could you identify it for the record? A. This is a prescription that I acquired from Dr. Kessler yesterday morning.

Q. And where is Dr. Kessler located? A. He's in Savannah, Georgia.

Q. Did you have a prescription filled? A. Yes, sir, I did.

Excerpts of Trial Proceedings

MR. RAUBICHECK: I show counsel an object which has been marked as Exhibit 90.

Q. Mr. Pangburn, would you — well, have you ever seen Exhibit 90 before? A. Yes, sir. I got this from Hillard's Prescription Shop in Savannah, yesterday.

Q. Could you identify it for the record? A. It's Cydel, 200 milligrams and the capsules [Tr. 12] are orange. Much the same as in this other bottle.

* * *

[Lipstein, Tr. 23] Q. And would you please state for the Court briefly your educational background?

* * *

[Tr. 24] A. Ph.D, Columbia University, MA, Columbia University. BA, Brooklyn College.

Q. And what courses do you teach at NYU? A. Marketing research, advertising research, quantitative methods in marketing, the marketing of financial services, design of experiments.

* * *

Q. Can you — A. I have taught other courses as well previously. Sample survey methods, statistical inference, analysis of variance, and other related statistical courses.

Excerpts of Trial Proceedings

Q. Can you also state briefly your employment history with special attention to any part of it that relates to either statistics or market surveys? A. Yes. Previous to being professor of marketing at New York University, I was director of research, Senior[Tr. 25] Vice President and member of the Board of SSE and B, Inc., an advertising agency of substantial size, world-wide, about 850 million dollars in billing. As director of research I was responsible for all surveys conducted for the agency or clients throughout the United States. I was also chairman of the sub-committee on research world-wide, responsible for instructing the offices around the world on the latest methods and statistics and survey procedures. This ranged from 1965 until I assumed the professorship in New York University.

Prior to that, I was associate research director, director of information services and the vice president at Benton and Bowles, also an advertising agency and had similar responsibilities, primarily for General Foods, in the design and execution of a wide range of surveys. Prior to that, I was technical director, vice president of Audits and Surveys, responsible for the design and execution of sample surveys. Prior to that, I was mathematical statistician with the Bureau of Labor Statistics, responsible for the design of national surveys that the Department of Labor executed, as well as a whole series of methodological issues that they were concerned with.

Q. Did you design and analyze a survey in connection with this lawsuit? [Tr. 26] A. Yes, I did.

Q. How did this come about that you did so? A. I was requested by counsel to examine the problem and recommend a research design.

Q. And I'll show you Plaintiff's Exhibit 62 and ask if you can identify that? A. Yes. This was a letter which I sent to Miss Driscoll, in terms of my view of the problem and how to approach it.

Q. And what was your understanding, sir, of the purpose of the survey to be done? A. The purpose of the survey was to determine the confusion that existed on the part of people who take Cyclospasmol and their ability to recognize or identify the generic product cyclandelate as Cyclospasmol. Or their confusion on the issue.

Q. And in your original proposal. did you initially intend to do the survey of patients only? A. Initially, yes.

Q. In fact, was the final survey done of patients only? A. No, it was not. It included doctors.

Q. Why was that? A. Because statistically, it was impossible [Tr. 27] to reach patients without first going through doctors.

Q. Why do you say that was statistically impossible. A. Well, there are at most 100,000 people in the United States who take Cyclospasmol. This represents a very small percentage of the total population. It would take an inordinately large sample to find even a handful of these people. It is essentially looking for a needle in a haystack. Statistically it is called a rare event or scarcity sampling. And it would be statistically impossible to execute.

Q. In other words, you are saying you couldn't go to, for example, shopping centers I know a lot of surveys are done in

shopping centers, could you have done that kind of random survey in this case? A. You could not have located any meaningful number of people through shopping center interviews and if you had taken a general population sample on an area basis, the likelihood of finding users of Cyclospasmol are almost nil. You simply compute the probabilities of 100,000 over roughly 200,000,000 population, you are dealing with a fraction of a per cent.

* * *

[Tr. 32] Q. And what category of physicians did you decide to use? A. I did not identify them in advance as to category.

Q. How did you identify them? A. The physicians — well, the first step was to determine roughly how many physicians there were in the United States.

Q. How did you do that? A. Who might be prescribing Cyclospasmol.

Q. Did you, in fact, determine how many might be prescribing Cyclospasmol? A. Yes. From IMS. IMS is a — one of the largest marketing research firms in the world, concerned with auditing of scripts that doctors write. From the IMS particular set of tables, I determined that there were some 32,000 general practitioners, full-time activity. There were some 12,000 part-time general practitioners. There was a lesser number of internists. Now, the IMS data showed that approximately 23 per cent of the general practitioners prescribed Cyclospasmol. If I multiplied that 23 per cent by the 32,000 doctors, I get an estimate of the number of general practitioners who prescribe [Tr. 33] Cyclospasmol. In the case of the part-time physicians, in discussion with the IMS people, who are

expert in this area, they suggested working with half of the part-timers which are roughly six or 7,000.

* * *

THE COURT: You are going to show that they can't tell one blue pill from another pill? And you're going to show that a certain percentage of them say that it is Cyclospasmol?

[Tr. 34] THE WITNESS: Yes, your honor.

THE COURT: When they looked at it?

THE WITNESS: Yes.

THE COURT: Because they had heard of Cyclospasmol before?

THE WITNESS: They recognize the blue —

THE COURT: They wouldn't know whether it was Cyclospasmol or not unless they heard of Cyclospasmol before that?

THE WITNESS: Exactly, your Honor.

THE COURT: What is the big deal? You can't tell the — you can't tell one pill from another because they both look alike. Isn't that — isn't the likelihood of confusion very high?

THE WITNESS: Well, that is — the study demonstrates that —

THE COURT: Do I need you to tell me that you can't tell one blue pill from another? It seems to me I would draw that inference myself. And if no one has heard of — if the only drug that they have heard of, let's say, a vasodilator or whatever, they've been taking, Cyclospasmol, I assume they'd say yes, that is Cyclospasmol?

THE WITNESS: That is essentially the findings.

[Tr. 35] THE COURT: What do I need him to testify to that for?

MS. DRISCOLL: Your Honor, I do want to put this survey in to create a record. Just to clarify what was involved in this survey, so that you know more what the significance was .

THE COURT: What is the significance of it? I don't see the — I don't understand the significance of it. Someone has been using Cyclospasmol. It is a blue pill and someone shows them a blue pill and says, what is that. They say surprise, Cyclospasmol.

MS. DRISCOLL: Your Honor, the defendants in this case are making the claim that if they put their names on their blue pills, there will be no confusion and that is part of this case, your Honor. May I show you what will later be marked? This is what was identified as Cyclospasmol. It says Premo on it.

THE COURT: So they don't look that closely. I assume that a lot of people don't look that closely. I really don't see what it has to do with your case, at any rate because you are not selling — they aren't going out and selling to the consumer. [Tr. 36] You have to persuade the doctor to prescribe Cyclospasmol.

Excerpts of Trial Proceedings

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[Tr. 38] THE COURT: You only talked to physicians who were prescribing Cyclospasmol?

THE WITNESS: Well, I did not know what these physicians actually prescribed. And I will explain the source of these doctors in a moment, but, presumably these doctors were primarily prescribers of Cyclospasmol.

THE COURT: So they weren't in any doubt when they wrote out the prescriptions of the difference between Cyclospasmol and some generic cyclandelate, were they?

THE WITNESS: I don't know, your Honor.

THE COURT: All right.

BY MS. DRISCOLL:

Q. Now, from what source did you get a list of actual physicians' names — of physicians who were believed to have prescribed Cyclospasmol? A. The Ives Laboratories provided me with a source of list of names. These names were requested by the Ives people from their detail men, requesting the names of physicians who they believed were [Tr. 39] prescribers of Cyclospasmol. This consisted of the name, address and their telephone number and zip code. There were approximately 12,000 such doctors. Now, these doctors were listed on a computer run that you have in front of you.

MS. DRISCOLL: Your Honor, this is Plaintiff's Exhibit 68. I won't burden the Court with it. It is the computer run of 12,000 names.

THE COURT: Yes.

Q. Now, I believe you stated that the list given you by Ives contained approximately 12,000 names, whereas you thought there could be as many as 15,000 prescribers. Does the difference in the total in your mind, affect the validity of the universe and of the projections you can make? A. No. First the — it might actually be as low as 13,800. So, we are dealing with the 12,000 names represent anywheres from 80 to 90 per cent of all doctors who presumably prescribe Cyclospasmol. In survey practice, that represents a very substantial portion of the universe to be surveyed and almost any finding that we determined for these 12,000 doctors, almost irrespective of what the residual group we did not include, might represent, would in no way materially affect the [Tr. 40] results.

Furthermore, the likelihood is that the roughly 1,800 to 2,000 doctors not on the list would probably have the same characteristic as those on the list.

Q. After this printout was presented to you, Dr. Lipstein, what did you do? A. I requested that the — this computer listing be arranged by zip code, from the lowest numbered zip code to the highest numbered zip code.

Q. Why? A. This provided me with an automatic geographic stratification of the doctors across the country.

Q. And how many geographical areas across the country did you think it appropriate to survey? A. I used 20 geographic areas across the country.

Q. Why did you select 20? A. For two reasons. One given that I wanted a sample of 100 observations, 100 doctors and 100 patients. I felt the work load of five doctors per interview, per interviewer, seemed reasonable, which would imply 20 locations. Also 20 locations is a reasonable number of locations for estimating a single national characteristic.

[Tr. 41] Q. Now, what is the basis for that conclusion? A. Prior activity and experience in the survey field.

Q. And how were the names of these specific doctors then chosen? A. Based upon the count of 12,000 doctors and the decision to take groups of five doctors, this determined the sampling interval, that is the rate at which I would select doctors through the list, and I then chose a random number from a table of random numbers between one and that sampling interval, and that determined — by counting from the top of the list of doctors to that random number — that determined the first group of doctors to be selected.

Thereafter, systematically going through the list, every nth group of doctors was then selected until the entire list was exhausted.

Q. And did anyone from Ives tell you which geographical areas to select? A. No, they did not.

Q. Or did anyone of them tell you which physicians to select? A. No, they did not.

Q. Now, once the geographical areas were selected, were there any substitutions made? [Tr. 42] A. Yes, there were substitutions made.

Q. And why? A. I discussed the area selection with the Harry Heller Research organization, who was willing to execute the study and with their Field Director. And they pointed out two things, one, that some of the areas selected did not have a sufficient number of doctors for the purpose of interviewing, and that would mean that the interviewer would not be able to complete the assignment.

And, secondly, that in some of these areas quality interviewers to conduct the interviews were not readily available to execute the study.

My experience had demonstrated that the interviewer quality is as equally important as the sampling area itself.

So with this in mind we permitted some substitutions. But these substitutions were always made within a geographical strata so they were essentially equivalent in terms of representation.

Q. Were these substitutions made before or after the survey interviews were actually begun? A. They were made before the survey was in fact begun.

* * *

[Tr. 49] A. Yes. This is the package which the interviewers carried with them with the various capsules in the jar.

MR. COBRIN: Is there a label on that?

THE WITNESS: There is no label on this Exhibit.

A. (continuing) The interviewer was then instructed to pour the capsules on the desk or the table between herself and the doctor.

And the question was asked:

Do you recognize any of these capsules?

Q. Now, there are a variety of capsules there.

Could you tell me why the particular capsules were selected for use in this bottle shown to the physician?

* * *

THE COURT: Well, just tell me which capsules they are.

THE WITNESS: Yes. There were three blue capsules, two blue without any markings at all, and one blue with the marking Premo on it.

There were three red-blue capsules, two without any markings at all and one with the name Premo on it.

THE COURT: There were none with IVES on it.

[Tr. 50] THE WITNESS: None with IVES.

Q. Why were there none with IVES, Dr. Lipstein? A. Because the physician might examine the capsules and see the name Ives and then associate Cyclospasmol with Ives.

Q. Was there an attempt to keep Ives out of it? A. That is right.

MR. COBRIN: Objection to the leading.

THE COURT: Overruled.

A. (Continuing) Yes, obviously if the name Ives were there we could expect that some physicians, perhaps a considerable number, might associate Ives with Cyclospasmol and therefore I couldn't measure what we were attempting to measure.

Q. And what are these other capsules?

Is there a maroon and white capsule? A. There is a maroon and white capsule which has the name Diazide on it. There were three of those.

Q. And what else? A. There was also a clear and brown capsule, one of which says Pavabid on it.

The other two, one has a small name here, Central, and the other one has nothing at all on it.

* * *

[Tr. 54] Q. Why was it decided to include a list of drugs in the final survey? A. It became clear, and this is a very normal process in survey design as you develop the survey instrument, that it was desirable to imbed the products we were concerned with in a relative framework. And I give you a kind of equivalent example, we have seen very often a familiar product imbeded in an unfamiliar background, and when asked to identify it you can't identify it — you really don't know what you are looking at — because this object is imbeded in an unfamiliar background. And if you take that object and imbed it

in a familiar background then you immediately recognize it for what it is. So it seemed appropriate to provide some sort of background from which, if there was an awareness, it would sort of position it.

Q. Would you identify 64-A, please? A. #64-A is called card A, which is a list of ten drugs which were shown to physicians.

Now, there were ten different versions of it.

Cyclospasmol is number one in the first card. It becomes two in the second card. It becomes ten in the 10th card.

We rotated the position of cyclospasmol to eliminate [Tr. 55] any possibility of what we call positional bias, that is, if Cyclospasmol had appeared always first it could have affected a subsequent response.

Q. Where did you get that list of drugs, Dr. Lipstein? A. Well, Cyclospasmol, Pavabid and Diazide were the three tablets contained in the jar.

I needed seven more drugs. And I took a list of the top 200 drugs that were prescribed by doctors and I selected seven random numbers.

THE COURT: Was that by brand name?

THE WITNESS: They are all brand names.

A. (Continuing) And I selected seven random numbers. And these random numbers determined the seven brand names that would be included on the list.

That is important for two reasons, one is that I wanted to introduce at every level I could some probability mechanism, because that is the nature of survey processing.

And the other is by using random numbers it avoided any biases of an unknown nature, or any adverse factors that might have affected the results.

Q. Why didn't you put cyclandelate on this list? A. It is not on the list of 200, and did not come in.

* * *

[Tr. 59] MS. DRISCOLL: Your Honor, I would now like to show the witness Plaintiff's Exhibit 71.

Q. I would ask you if you know what 71 is?

MR. COBRIN: Are those the physician's forms? A. Yes. These are the physicians forms.

Q. I notice that the names, and addresses and telephone numbers of the physicians are whited out? A. Yes.

Q. Why was that done? A. One because — so that confidentiality was assured to the physicians.

Furthermore, it is a common practice, for example, the Census Bureau, the Bureau of Labor Statistics, and all Government Agencies assure all their respondents of the confidentiality of responses to statistical surveys.

That is standard Government practice that has existed for certainly 40, or 50 years if not longer.

It is also common practice, in marketing research to assure respondents that their identification will be held confidential, particularly with respect to something involving physicians and drug prescriptions, it seems to be all the more reasonable.

[Tr. 60] Q. Now, the physicians were also asked, were they not, on page three of the questionnaire if they can furnish the patients' names? A. Yes.

Q. Did they all do so? A. No, they did not.

Q. Were they given any criterion for selecting the patients whose names should be given? A. Only that they be able to respond, that is, that they be reasonably mentally alert.

Q. Now, does the fact that physicians in fact made to some extent the selection of the people to participate in the patient interview in your opinion bias the results of the patient interview? A. I do not believe so because the physician would have no particular reason first of all to select one patient verses another nor would he necessarily know what our objectives were. So I cannot see how any bias would enter into it through the physician's point of view.

Q. Were any payments made to the physicians that participated? A. Yes. They were paid a normal fee for an office visit.

And in addition a payment for names provided of [Tr. 61] patients who have been prescribed as cyclospasmol.

Q. Why was that second payment made? A. To encourage them to provide us with names.

Q. Was the payment for the work they would have to do? A. Presumably.

Q. Is it unusual to make a payment to a respondent in a survey interview? A. It has become more and more common practice to pay a respondent either with some small token gift or payment.

Even yesterday I received a questionnaire in the mail from a magazine, and attached to it was a dollar.

In effect I am not obligated to answer, but they were in effect paying in advance to encourage me to answer the questionnaire.

* * *

[Tr. 63] Q. Did you in fact in any instance hear the conversation between the doctor and the patient? A. No, I did not.

Q. Do you have any reason to believe that a patient would give incorrect information in response to question one?

* * *

A. I don't believe so and in inspecting the questionnaires, I do not recall a single questionnaire in which the patient reported that the doctor or nurse had told him about the intentions or content of the survey.

Q. I'll now show you Exhibits 88-A through C and 89-A through C, which are six prescription bottles. Would you identify the 88 group? A. The 88 group are three different

containers, with different closures, containing blue capsules without any — one of them contains blue capsules without any markings. The second one also contains blue capsules, but this one sort of lifts off, again without any markings [Tr. 64] and the third one again contains blue capsules. Notice the closure of this one is different, and this one has the name Premo on it.

Q. And do those bottles also have labels? A. Yes, they do.

Q. Do the labels say cyclandelate? A. Yes.

Q. Does the one in your hand now also say Premo? A. Yes, it does.

Q. Would you identify 89 and do it very briefly since it's parallel? A. 89 is exactly the same except that it contains the red and blue capsule. One of them has the name Premo on it.

Q. Do all of the labels say cyclandelate? A. Yes, they do.

Q. Do they all also have a name on it, such as Inwood, or MD, or — A. Inwood, Premo and Rugby.

Q. Why were those particular capsules selected for this as opposed to using an Ives capsule? The same reason as in the physician — A. Exactly the same reason.

Q. Why were three bottles shown? [Tr. 65] A. Well, one, it was to distract to some degree. In other words, the emphasis initially was on sort of opening the individual jars. And there was one with identification on it as opposed to the others which were not. So that if you had — you had in effect writing on one capsule and not on the others.

Q. Now, after the initial questions were asked, were the patients, if they could not identify the drug, were they also shown a list? A. Yes, they were.

Q. Would you identify 65-A? A. 65-A is called Card B and has a list of ten drugs on it, again the first one on this one is Cyclospasmol, 9 other drugs, and the position of Cyclospasmol is rotated so that Cyclospasmol would not have what we call a position bias. Again, I made the selection of the remaining nine drugs. I used again the random number approach and the seven drugs that were selected for the doctor card were included in this and I selected two additional random numbers, to extend the list to ten for the patients.

THE COURT: Were those all — are they all brand names?

THE WITNESS: They were all brand names.

* * *

[Tr. 73] Q. Now, this study and the interview reflects an absolute number of people who made the identification you are referring to. Now, is it your belief that these absolute numbers can be projected to the entire universe of Cyclospasmol prescribers and users? A. Yes. The study design was constructed to provide for projection to the entire universe of doctors who prescribe and patients who take Cyclospasmol, through the random start and the systematic selection of the doctors throughout the list and the follow through with the individual doctors. So that one can quite comfortably say that these numbers are projectable to the entire population of physicians who prescribe Cyclospasmol and for patients who take Cyclospasmol.

Q. Now, in making this projection, to the entire universe is there a margin for error? A. Every survey is subject to a margin of error.

* * *

[Tr. 83] Q. I now show you Plaintiff's Exhibit 83 and ask if you will identify that? A. This is the report which I prepared, summarizing the findings of this shopping activity.

Q. Can you simply, the Court does have a copy of the — can you just point out the more significant findings? A. Yes. If you'll turn, let's see, 2, 3, 4, 5, pages, to the first table, which lists the Ives list of pharmacies and at the base, the second table down, it says, Prescription labeling when cyclandelate dispensed by pharmacists, we find that there were total in this particular list of 18 pharmacists who dispensed cyclandelate but in fact, cyclandelate dispensed and labeled as Cyclospasmol by 6 or 33 percent.

We turn to the next page. The table again at the lower part of the page prescription labeling when cyclandelate dispensed by pharmacists, and again there [Tr. 84] were 17 pharmacists who dispensed cyclandelate, and of those 17, cyclandelate dispensed and labeled as Cyclospasmol by four or again by 33 percent. Since — this is from the Hayes directory. And since the results of both the Hayes directory and the Ives list were literally almost identical, statistically the same, I felt free to combine the two into a total combined sample of pharmacists and when one looks at the next page, —

THE COURT: What were they asked? What was the prescription they were asked to fill?

THE WITNESS: The prescription, if I may show you, was for Cyclospasmol.

MS. DRISCOLL: The substitution permissible, your Honor.

THE COURT: Were substitutions permissible?

MS. DRISCOLL: Yes.

* * *

A. (Continuing) Now, because the results of both the Ives sample and the Hayes directory sample were almost identical, statistically, I was able to combine the two and in the third table, we have the combination of the two samples, which is now projectable for the State [Tr. 85] as a whole, in which we have a total of 35 pharmacists who dispense cyclandelate. Of those 35 pharmacists, ten, or approximately 29 percent had on the label cyclandelate and when they — rather they dispensed cyclandelate and labeled it as Cyclospasmol.

THE COURT: Did you have any — did you have any prescriptions that said — didn't say substitution permitted. Dispensed as written; is that what it says?

THE WITNESS: I don't — I believe they were all the same.

THE COURT: All said substitution permitted?

THE WITNESS: They all were the same, I believe.

THE COURT: All right.

THE WITNESS: Substitution permissible.

MS. DRISCOLL: Yes, your Honor. If I may speak to that? This was not for the purpose of showing illegal substitution, but for another purpose.

THE COURT: Okay.

Q. Now, may I please just note for the record that the boxes of exhibit — of those exhibits are 82 and I have marked as 82-A the copy of the prescription that [Tr. 86] Dr. Lipstein took from one of the envelopes.

THE COURT: There is no survey been made or shopping done to show what percentage of pharmacists make an illegal substitution that you are going to introduce?

MS. DRISCOLL: No, sir.

* * *

THE COURT: All right. Did any of the bottles say generic equivalent or have any letters or anything to indicate that it was generic? Did you make that analysis?

THE WITNESS: Yes. There was some — there were some labels which said Cyclospoasmol and then in brackets, generic.

THE COURT: What percentage were those that [Tr. 87] had in it generic?

THE WITNESS: I'd have to go back and read —

THE COURT: You didn't make that calculation?

THE WITNESS: No.

* * *

[Tr. 94] Q. Could you point out to me — which exhibit number is it, so the record will be clear? A. 67.

Q. Could you point out to me where in the — in the instruction sheet it advises the interviewer to tell the patient that his name will be kept confidential? A. I am not sure I could find that.

Q. Isn't that because it is not there? A. I'll take your word for it.

Q. You don't have to take my word. You can look at it.

* * *

Q. I simply assume there is no instruction to the interviewer that the patient was told that he — that his name was to be kept confidential? I'm sorry. The doctor. [Tr. 95] A. Again, I do not recall that there is a specific statement in it. If you say there is not, I would take your word for it.

Q. Okay. What was your understanding of why the survey was commissioned? A. The purpose of the survey was to determine confusion that existed among doctors and patients in identifying a blue and a blue red capsule.

Q. Was it for secondary meanding? A. I am not sure that I understand what secondary meaning is.

Q. Do you feel ill at ease using the term secondary meaning? A. Yes.

Q. Its not a term that you have heard, I take it? A. I have heard it used on occasion, but I still am not certain that I could interpret it properly.

Q. What do you think your cousel hoped the survey would find and prove?

MS. DRISCOLL: Objection, your Honor.

THE COURT: I will let him answer that.

A. Well, in a way — to my mind, it — I didn't care what they hoped the survey would prove. I was [Tr. 96] simply executing a research instrument. I presume they were hoping to observe reasonable levels of misidentification. But that was irrelevant to me.

Q. I take it that you wanted the survey to be as objective as possible in the implementation? A. I tried my level best.

Q. And the reason you wanted it to be objective was that we all recognize, I take it, that if there are any bias built into the survey, it can affect the result, is that not correct? A. That is true.

* * *

[Tr. 128] Q. Isn't it a fact that every interviewer was expected to review the questionnaire before he went out and conducted his interview? A. Yes.

Q. As a result of that, every single interviewer knew that Cyclospasmol was the subject of the survey? A. In a way, yes.

Q. Is it yes or no? You said in a way. Can you answer directly? A. Well, they knew that Cyclospasmol was the drug we were looking for for patients. Precisely what we were looking for. I don't think they could have determined.

Q. All I asked you, every interviewer knew that the survey was about Cyclospasmol? A. Yes.

Q. Didn't the card that was shown to the physicians substantially raise the incidence of identification? A. It increased it.

Q. Substantially? A. I will have to look at the tables to answer you.

No.

* * *

[Tr. 131] Q. If it wasn't representative you couldn't extrapolate? A. If it was not representative, it could not be generalized.

Q. Do you have Premo's Exhibit 26, September 24, 1979's proposal?

MS. DRISCOLL: I think that is Plaintiff's Exhibit, not Premo's.

THE COURT: It is 62.

MR. COBRIN: That is the number we used.

THE COURT: We'll go by the Plaintiff's since it is already in evidence.

MR. COBRIN: Okay.

Q. Can you turn to page four at the back which says, "research proposals continued"? A. Yes.

Q. In paragraph five it says, "patient will be shown sample of the Ives brand and its generic counterpart and asked to identify which is his brand of drugs." A. Yes.

[Tr. 132] Q. This proposal, I take it, was sent to counsel; was it not? A. Yes.

Q. And that test in number five was never utilized, was it? A. That's right.

Q. Now, in number three, it says, "interviewer, built to identify brand names of drugs.

Do you see why I am referring? A. Yes.

Q. This proposal was sent to counsel, wasn't it? A. Yes.

Q. And was it built to identify brand names of drugs included in the patient questionnaire or the physician's questionnaire? A. This proposal was a very early —

THE COURT: Just answer the question. Was it or wasn't it?

THE WITNESS: No, it wasn't.

Q. In number six —in number seven, the individual is asked to compare his own product with both the Ives and generic product and asked if he's able to tell which product he's currently using. A. Yes.

* * *

[Heller, Tr. 206] Q. How large is your staff at your headquarters in Port Washington? A. Our staff in Port Washington is approximately 25 people of which 15 are permanent people and another ten are brought in for specific projects.

Q. Do you have your own staff to do the field work in a study such as the study involved in this case? A. No, we do not.

The traditional way of doing field work in marketing and public opinion research is for the research company to contract with independent contractors throughout the country.

There are only one or two companies that have the luxury of their own field staff, and even in those the field staff is not nationally representative.

Q. Do you have an ongoing relationship with certain field supervisors you have used in the past? A. Yes, we do. We have used them as a company for [Tr. 207] seven years. And individuals in my company have worked with these field staffs for as much as 25 years in some cases with the same person.

Q. Has there ever been an occasion when you have been dissatisfied and had to terminate your relationship with a field supervisor? A. That has happened from time to time, yes.

Q. Now, in how many geographical areas did you have a field supervisor doing the interviews in connection with this particular study? A. 20 geographical areas.

Q. And where did the geographical areas come from?

Was there a list initially given to you? A. There was a computer run of physicians that was supplied to us. And the actual choice of the geographical area was done by a random number that was given to us by Dr. Ben Lipstein. And using the random number, and a specific skip pattern, we selected 20 geographical areas.

We then took those areas to see whether interviewers were available in those areas.

In cases where interviewing services were not made in that area we made a substitution to a chosen zip code area.

[Tr. 209] Q. And I asked if you can identify them? A. Yes. Plaintiff's Exhibit 66 is the administrative instructions which is a set of instructions that we prepare instructing our independent field supervisors on how we want the study conducted.

And Plaintiff's Exhibit 67 is the interviewing instructions which are written by us to instruct the interviewer as to how to go about conducting the interview.

Q. And did your firm have the final say as to what was to go into those instructions? A. Our firm submitted the instructions, as we usually do to our client, to make sure that anything in the instructions were not particularly out of order. But the specific wording and the way it was phrased was determined by our firm.

Q. And has any member of your organization ever received any award for drafting field instructions? A. Yes. My Director of Operations and Vice President, Miss Doris Lesansky —

MR. MARROW: I object to that, your Honor.

THE COURT: I will listen to it.

She drew good instructions.

MR. MARROW: What is it suppose to prove?

MS. DRISCOLL: Your Honor, I am not going into [Tr. 210] for frivolous reasons. But we do want to establish that every precaution was taken to select someone who would execute this survey properly. I am not doing this frivolously.

A. (continuing) And my V.P. Director of Operations, Doris Lesansky, was given the Silver Cup Award with respect to the Market Research Association, which is a national public interviewing organization, for excellence in field instructions, and she won that top award after two years of being the honorable mention. To get this award she has to demonstrate top facility in preparing instructions.

Q. Did she participate in the execution of this particular study? A. Yes, she did.

Q. Now, after the interviews had been sent to the field, what was the next step performed by Harry Heller Research? A. After the interviews were sent to the field we were in daily contact with the field to make sure as to how the study was being conducted.

The interviews were sent back to us and we submitted the interviews to an approach called validation, in which a sample of interviews from each interviewer is given to an independent company, and the company makes long [Tr. 211] distance telephone calls to make sure that the interview was conducted properly.

We asked certain questions to make sure that the interview was properly conducted.

THE COURT: Of whom did you ask those questions?

THE WITNESS: Of the respondent in the state.

THE COURT: You called the patient and you called the doctor?

THE WITNESS: Yes, this is correct.

Q. And would you identify for the record Plaintiff's Exhibit 76 please? A. Yes, sir. This is a letter from the company that does our validations. It is called Centrac Incorporated in New Jersey, demonstrating that they were given 141 listings and they had called at least a number of respondents for each interviewer. And they found no problems in the execution of the study by the interviewers.

Excerpts of Trial Proceedings

THE COURT: What is the company that does the validation?

THE WITNESS: Centrac?

THE COURT: Oh, yes, Centrac.

So you had to give them the doctors' names and the patients' names and telephone numbers?

THE WITNESS: We give them a sheet of paper [Tr. 212] with the name, the telephone number and a list of validation questions.

THE COURT: And that is to assure yourself that in fact the questions that were on this questionnaire were properly asked?

THE WITNESS: Were properly asked, that is correct.

THE COURT: That didn't suggest anything to them, that type of thing?

THE WITNESS: That is correct.

THE COURT: How many did they call?

THE WITNESS: We asked them to validate at least 20 percent of each interviewer's work which meant on the average of one person per interviewer.

In the event there was any problem they were authorized to make additional calls.

THE COURT: Did you run into any problems on any of those?

THE WITNESS: No.

THE COURT: Not one single problem?

THE WITNESS: No, your Honor.

Q. Is that reflected in your report in front of you? A. Yes.

[Tr. 213] Q. Is it the ordinary practice in survey work to have validation work done by a company other than your own? A. This is done all the time by us.

Q. Now, did you participate, Dr. Heller, in the decision not to disclose in this case the names of the physicians and patients who had responded to the interviews? A. Yes, I did.

Q. And can you tell me what considerations you took into account in participating in that decision? A. The confidentiality of what we call respondents in survey research is almost a "given" in the marketing research profession.

Our organization is a member of the Council of American Survey Research Organizations, CASRO.

And in the business practices guidelines, this procedure is part of the CASRO policy.

In addition the United States Government in the Census Bureau has also established the fact that names of people

interviewed as part of surveys done for the Census shall not be divulged to anyone.

The only exception to this is just for the purpose of validation.

[Tr. 214] Indeed very often we tell the Respondent that the only reason we are taking their name is just for validation.

The assumption in the industry has always been that in dissemination of the names of the respondents in a survey could be used to either further contact them or might institute undue harrassment of the respondent. And that would cause us serious problems in gaining public cooperation in surveys.

THE COURT: Is it because it might affect future surveys that you do not want the doctors and patients interviewed in the future.

THE WITNESS: Not necessarily future surveys. It is to effect — it's because the cooperation for the future was obtained with the promise that their name wouldn't be used.

THE COURT: Let us assume you went in and didn't promise confidentiality, would that create a problem?

THE WITNESS: I think what it would do is it would reduce the cooperation rate to a lower level than it was.

THE COURT: You would still get some cooperation but not as much.

[Tr. 215] THE WITNESS: Yes, that is correct.

Excerpts of Trial Proceedings

THE COURT: That would be the effect of it?

THE WITNESS: Yes.

THE COURT: All right.

BY MS. DRISCOLL:

Q. Dr. Heller, I show you what has been marked as Plaintiff's Exhibit 86 and ask you if you will simply identify it for the record? A. Yes, that is the CASRO code of standards for survey research.

Q. What what is CASRO again, sir? A. It is the Council of American Survey Research Organizations. It is a group of 50 of the top public opinion research companies, along with our firm, such companies as Yankelovich I think it is, but that is close enough, and Gallup, and Market Facts, and Nielsen, all belong to it.

It is the group that establishes basic business practices and standards for a specific industry.

Q. Dr. Heller, are you aware that there were a fair number of physicians who either could not be contacted or who indicated no interest in participating? A. Yes, I am aware of that.

* * *

[Tr. 217] Q. Is there any way for you to determine from the questionnaires that were used whether a third person was present when the field interviews were taking place? A. No, there is no way of determining that.

I would say that having a third person available at the interview would be a tremendous departure from practice that interviewers are trained in all the time for the interview as between them and the respondent.

Q. Now, was the report sent back to your organization, the completed interviews, at some point? A. Yes. They sent back completed interviews.

Q. What would your staff do at that point? A. Well, the next thing we do is we went through a process called editing and coding in which the responses to the questionnaire are looked at, and an attempt is made to classify them and assign numbers to them so that they could be put on IBM cards or other data processing things can be done to them.

So they went through our coding and editing process, and after completion of that phase of the study we then had the cards keypunched and verified with the keypunching, and ran computer tabs which simply counted the number of responses in each category of the questionnaire.

[Tr. 218] Q. Do you know whether in tabulating the results your staff rejected any of the material that was sent out from the field? A. I know of several cases in which — as a matter of fact they came to my office on it — in which there were questionnaires that were rejected because the interviewer had failed to ask one of the questions in the questionnaire.

And we felt that rather than counting the interview anyway, since that question was there, we wouldn't count it at all.

Q. Would you be the person who would make the decision as to rejection or not in circumstances like that? A. In this

particular case where there was a judgment I was the one that it reached.

But there may be other reasons for rejecting an interview that is made at a lower level than me, depending upon the way it is asked.

Q. Now, do you recall that in both the physician and patient questionnaire at some point if there had been no spontaneous response, the patient or physician was shown a list? A. Yes.

[Tr. 219] Q. Now, was the interviewer supposed to indicate on the form in which order the name Cyclospasmol was on the list given to the particular person? A. Yes. There was a line providing for the interviewer to write in a number between one and 10, according to the position on the list, whether Cyclospasmol was there.

Q. Was there ever an indication when the interviewer did not fulfill that requirement and indicate where it was on the list? A. Yes. We found, I believe, in the case of two of the physicians and in the case of three of the patients the interviewer failed to put the number there in the order.

Q. Were these questionnaires counted? A. They were counted in both cases rather than — yes sir, they were counted. In both cases the order was not critical to the result because in neither case was the patient — in two of the three cases the patient didn't even identify Cyclospasmol so therefore the order in which it was could not have biased the response.

Q. If they had not been counted presumably the results would have been more favorable to Ives position.

Is that right? [Tr. 220] A. Yes, that is right.

* * *

[Tr.222] Q. What is a typical sample size for a national survey? [Tr. 223] A. Well, that would depend upon the subject matter.

If it were to reflect a presidential election it might be between 1,200 and 1,500.

But I have done national surveys among architects on their specifications of door locks in which it was judged that 85 to 150 interviews were an adequate number of interviews.

Q. Have you ever done a national survey where your population size was about 200,000? A. Never.

You said 200,000?

Q. Right. A. That is right. Never.

Q. Have you ever done a survey where you had an 80 percent rejection rate, or refusal to speak to you? A. Yes. It is ordinary among physicians.

In doing the National Eye Care Study among opthomologists [sic] for Corning Glassworks, the refusal rate on Opthomologists [sic] was about 75 percent.

And the talk in the industry generally, experience in the industry among physicians, is that in getting physicians, non cooperating physicians, namely, where the survey is the first time

we are asking them to cooperate, refusal [Tr. 224] rates as high as 80 percent are traditional.

* * *

[Tr. 226] Q. Do you remember during your deposition, you discussed toastem pop ups? A. Yes.

Q. You said when the product became generic, the people would call the generic product Toastem pop ups? A. Yes.

Q. Isn't it true with a drug that you would have the same situation? Speaking used to taking the branded [Tr. 227] product, when they started to take the generic, they would call it — even though it wasn't the same product, the same as with toast em pop ups? A. The toast em pop ups was in a different context then this.

What I had said about that, is that — is that — very often people come to refer to the product itself in terms of the best known product in the area.

Q. They use it to describe the product? A. That's right.

* * *

[Tr. 232] Q. The people who conducted the interviews were the respondents knew it was for litigation: Your answer: Yes, as a matter of fact, they were instructed if I am not mistaken to complete the questionnaire and do other procedures that are traditionally done." When you gave that testimony last Thursday, you thought that was accurate? A. Yes. I believe these instructions are Exhibits 66 and 67.

Q. When I asked that question you understand that I was speaking to the people speaking to the respondents, didn't you? A. Our communication to the interviewers is Exhibit 67.

Q. That is not the question. A. That is the only communication that we have.

Q. All I am asking you when you said that the interviewers who dealt with the respondent knew that it was for litigation. When I asked you about that, you understand the question you had no problem with it? A. That is correct.

* * *

[Bernstein, Tr. 234] Q. What does a field director do? A. A field director is in contact with the field, letters them for jobs, supervise as the job is in progress, calls the field to get bids on different jobs, checks over the interviews when they come back, basically that is my function.

Q. Did you perform those functions in connection with the interviews — survey that was done in this case? A. Yes, I did.

Q. With whom was your contact in the field? A. With the supervisors.

Q. Did you speak to interviewers? A. No.

Q. Just supervisors? A. Yes. I'm sorry, there were a number of times when I called for a report and the interviewer was in the supervisor's office.

She then got on the phone and gave me her report herself.

Q. Did you ever disclose to an interviewer that the survey was done for litigation? A. No.

* * *

[Tr. 239] THE WITNESS: If the capsules were not all the same, then we would certainly be told about it. If the name on the bottle would be — would say something and the pills didn't say something, then we were told about it.

THE COURT: Which bottles are we talking about?

MS. DRISCOLL: These are the bottles in Syracuse and Dayton —

THE COURT: These are the ones purchased?

MS. DRISCOLL: Yes. There was testimony yesterday about them —

THE COURT: I understand now.

Q. I show you what has been marked Plaintiff's Exhibit 109 and I ask you if you can identify that? A. Yes, I can.

Q. What is it? A. That is a letter to all the supervisors on the study telling them that somebody might contact them to ask them questions about our survey. Telling them that we accept full responsibility for the survey and that [Tr. 240] they should provide, since they have control over their interviewers.

MS. DRISCOLL: This is in connection with the problem raised this morning.

Q. Did you ever tell a field supervisor not to cooperate with an attorney or research organization that might call them about that? A. No, I wouldn't say anything like that.

Q. Was that your sole communication, Exhibit 109, with the field on this matter? A. Yes.

MS. DRISCOLL: I have no further questions.

Your Honor, I think in your question you inquired whether the bottles were purchased. That wasn't a purchase. You will recall the testimony said that Mr. Bovoso and Miss Brady went up and exhanged —

THE COURT: Excuse me, yes.

MS. DRISCOLL: It was that as opposed to some of the others that were substitution problems.

* * *

[Milnamow, Tr. 244] Q. Are you employed? A. Yes.

Q. Is it Mrs.? A. Yes, it is.

Q. By whom? A. By Harry Heller Research.

Q. What is your position? A. Coding director.

THE COURT: Pardon?

THE WITNESS: Coding director.

Q. Can you describe for the Court what a — the duties of a coding director are? A. Well, my function is basically as the Court has been over with Janet —

THE COURT: You're referring to Mrs. Bernstein?

THE WITNESS: Yes. She receives the interviews in her Department. After she receives the interviews and checks them in, they are given to my department.

Now, we check basically the count of the questionnaires that come in and then we process them, we put them in number order, and then we do an editing job. We edit the questionnaire [Tr. 245] to see whether the skip pattern has been followed, whether they followed the instructions and then after that we will then, if that seems to be all right and everything is fine, then we build a set of codes according to the answers that are given.

This is all to prepare the questionnaires for the keypunch for the data house.

Q. And are you aware that the brand name of the drug that was listed on some of the questionnaires is Cyclospasmol? A. Yes, I know.

Q. Are you also aware that in some of the returned questionnaires there were words somewhat like Cyclospasmol, Cyclospastic was one of them? A. Yes.

Q. And Cyclospasmol was the other? A. Yes.

Q. Who would make the decision whether words such as that were treated as a correct or incorrect answer? A. That would be my decision.

Q. Did you make the decision with respect to Cyclospasmatic that it would be counted as a correct answer? [Tr. 246] A. Yes.

Q. Were there similar words like that that you did not count? A. There were a couple of instances where there were words such as cyclo something or other or cyclo where it wasn't sufficient what the person was going to say.

Q. They were not counted? A. They were not counted as correct answers.

Q. Were there any other questionnaires that were rejected completely and did you play any role in deciding what was to be rejected completely? A. There were I think about four questionnaires that came in that the proper skip pattern was not followed.

Now, that was not my decision because in some cases we'll use that material.

However, I have a project director that I report to.

Now, that was discussed and it was decided that there was not enough information, since they did not recognize cyclospasmol according to the capsule that was shown and then they did — we didn't know whether they saw the cards physically or didn't. Since we count [Tr. 247] material whether they did see the cards, they were not used.

Q. Do you know of instances in which a completed questionnaire came in that you did not review? A. No, I do not.

Q. And did you either record or decide to reject every single one of the questionnaires? A. Yes.

* * *

[Lavalle, Tr. 261] Q. Mrs. Lavalle, are you employed? A. Yes.

Q. By whom? A. Myself.

Q. And what is the name of your company? A. Lavalle Research.

Q. What does Lavalle Research do? [Tr. 262] A. Market research firm and field interviewing.

* * *

[Tr. 263] How did this come about? A. We were contacted by the Heller Research to do a study concerning doctor and patients.

Q. Had you done work for Heller Research in the past? A. Many times.

Q. Were you told by Heller Research that the survey was to be used in connection with litigation? A. No.

Q. After being contacted, what did you then do? A. I contacted an interviewer.

Q. Did you anticipate when you heard that the survey was — what the survey was to involve that you might have problems? A. Yes.

Q. Why did you think you would have problems? A. It is generally very difficult to get to see any professional, most of all a doctor.

Q. What is the basis for your saying that? A. Several other studies throughout the years dealing with doctors.

Q. You have had to interview doctors in the past and had difficulty reaching them? [Tr. 264] A. Yes.

Q. In your years in the research field, have you noticed whether or not the willingness of people to cooperate in surveys has generally declined or remained the same or gone up? A. Declined.

Q. You have more trouble now then you did in the past in getting cooperation? A. Very much.

Q. And in your experience, is it unusual to offer a participant in a survey a gift or some monetary compensation? A. No, it is quite usual.

Q. And is it usual or unusual to indicate that you are making that offer before you actually ask the interview questions? A. Once the eligibility has been determined, it is usually before the interview has begun.

Q. What do you mean by determining the eligibility? A. So that it wouldn't sway the respondent in any way to become eligible for the study. Once those questions have been gotten through then to set up a little better rapport between you and he, you do tell him that there will be a gift at the end of the interview.

Excerpts of Trial Proceedings

* * *

[Caraccio, Tr. 293] Q. Are you employed, Mrs. Caraccio? A. Yes.

Q. By whom? A. Lavalle Research Company.

Q. How long have you been employed by Lavalle? A. Since August.

Q. What is your position? A. I am an interviewer, I edit, I do office work, whatever.

Q. Did you participate in as an interviewer in connection with the survey we're discussing today? A. Yes, I did.

Q. At the time you participated, did you know the identity of the client that had commissioned the survey? A. Harry Heller, I did.

Q. Did you who his client was? A. No.

Q. Do you know today? A. No.

* * *

[Lawlar, Tr. 307] Q. Do you hold any positions in any professional societies? A. I am currently the president of the Pharmaceutical Society of the State of New York.

Q. In your pharmaceutical practice, Mr. Lawlar, do you purchase drug products containing the same [Tr. 308] active ingredients in the same dosage strength from more than one source? A. Yes, sir.

Q. Is this a common practice in your pharmacy? A. Yes.

Q. Are such drug products from different sources made in different colors? A. Yes, surely.

Q. How often? A. Frequently.

Q. For what reasons do you carry the same drug from more than one source? A. The pricing is one. One company is offering it at a lesser price than another, balancing inventory.

Q. Any other reasons? A. Not really. Convenience.

THE COURT: Well, I take it some physicians prescribe by brand name, don't they?

THE WITNESS: Yes, sir. They do.

THE COURT: So you have to have the different brands if they have different colors?

THE WITNESS: That's correct.

Q. Do you maintain patient profiles of your [Tr. 309] customers at your pharmacy? A. Yes, we do.

Q. Because of a change in prescriptions and by that I mean at one time you filled a prescription for a particular patient for a particular drug and the next month that patient came back with a prescription for the same drug but as Judge Nickerson mentioned, a drug made by a different company under a different brand name, have you ever dispensed because of such a change in prescription to the same customer, the same dosage,

the same drug and strength that was different from the drug that the patient had previously been taking but the new medication was of a different color than that previous medication? A. Yes, I have.

Q. Has that —

MR. MARROW: May I have the question read back.

THE COURT: Yes. I think there was a misword in there, what you mean is, I think, it's the same drug generically?

MR. RAUBICHECK: Yes.

THE COURT: One time they had it in one color and then you fill it for them in another [Tr. 310] color.

Is that what you meant to say?

THE WITNESS: That is what I understood, yes.

* * *

Q. Has this occurred throughout your career as a pharmacist? A. Yes.

Q. Would you give examples of drugs which you have dispensed which have been made in different colors to the court, if you can? A. Ampicillins, there are eight or ten different companies I am familiar with that all make different colors of ampicillins, tetracyclines are all in different colors, certain anti inflammatory drugs, the hormones, different companies making the same sort of, same generic drug in different colors.

Many, many different ones, with the advent of the generic substitutions law, tremendous different colors.

Q. Have you ever received any inquiry from any of your customers concerning a drug that you dispensed, [Tr. 311] the same drug of a different color in a subsequent prescription?

Have any of your customers ever questioned you about the change in color? A. They had and we tried to head that over by telling them it's a different color but the same medicine.

Q. You communicated that to your customer? A. Yes, we do, we have a little sticker that we put on the bottle to remind us that it's a different color but the same medication, same drug.

Q. Has it ever happened that the patient, despite your efforts came back to you and explained to you about the change in color? A. I guess so.

Q. What do you tell the customers? A. We explained the color was changed because it's a different brand, or a different strength, and sometimes it's a different drug and they say, okay, fine.

Q. In any such instance because of the change in color, after you explained the situation to the customer, has the customer refused to accept the new medication? A. Never.

* * *

[Tr. 315] Q. You filed an affidavit in this case, did you not? A. I did, yes.

Excerpts of Trial Proceedings

Q. I want to read from paragraph 6:

"When I tell a customer the drug product [Tr. 316] I am dispensing is from another source which accounts for the difference in appearance.

It has been my experience that when some patients ask questions all but a few accept the medication despite the color difference."

I assume at the time you submitted the affidavit in the case, which was June 1978, that the affidavit was true and accurate, is that correct? A. I would assume so.

* * *

[Tr. 318] Q. Have you ever had a patient come in and refer to his drug by colors, such as my red water pill, or my blue heart pill or something to that effect? A. I have.

Q. Do you know what a maintenance drug is? A. Yes, sir.

Q. What is it? A. It is a drug that is prescribed for over a long period of time for a chronic condition.

* * *

Q. Would you agree with me that cyclandelate is a maintenance Drug? A. Yes, sir.

Q. Antibiotics, are they maintenance drugs? A. No, sir.

Q. In other words, a patient might get a prescription take it for a week or so, hope that it will get better and that is it for the medication? [Tr. 319] A. Generally speaking.

* * *

Q. Do any of the people who come into your pharmacy co-mingle their drugs, that is to say, they have a daily regimen of drugs in a single pill box, or something like that? Are you aware of such instances? A. A few.

* * *

Q. You said that you talked to the patients when there is a change of color and would reassure them — I understand your current testimony to be they all accept your reassurance, is that correct? A. That is correct.

Q. How do you handle a situation where you have a Russian immigrant who just came to this country and doesn't speak English, and has been on medication for a month or so, [Tr. 320] and the color has changed? A. I never had that happen, sir.

THE COURT: They do not have that many in Harrison.

Q. Have you ever had it with a person who doesn't speak English, say a person whose native language might be Spanish? A. I don't recall, no sir.

Q. When there is a change in color I take it that it takes extra time for you to explain to the patient that they are getting the same medication only in a different color? A. I think that is part of the process of the pharmacists explaining the drugs.

Q. Do you explain the medication to every patient that comes into your store? A. As often as I can, yes sir.

Q. And does it take extra time when there is a change of color and there is colloquy between you and the patient? A. It takes an extra second or so, surely. It takes a few seconds.

* * *

[Tr. 323] Q. I do not want you to guess. If you know, please tell us. A. I don't known the name. I do have a generic. I do not know the manufacturer of it.

Q. Do you have any companies where you do know? A. Lederle, Squibb, Parke Davis. Those three anyway.

Q. Parke Davis is not a generic drug company, is it, in the sense that they detail drugs, don't they? A. They have a detail man, yes.

Q. Parke Davis Tetracycline doesn't sell as Tetracycline? It has a brand name, doesn't it? A. It does.

Q. Dexamethasone, what is that Drug? A. It is an anti-inflamatory, cortisone.

Q. Is that an anti-inflamantory drug? A. Yes.

Q. Is that a cream? A. Yes, it does occur in a cream. But the dosage form that I guess I mentioned before is a tablet.

THE COURT: It is not a capsule?

THE WITNESS: It is not.

Q. Who is the brand leader of dexamethasone? [Tr. 324] A. A pure guess, Merck Sharp and Dohme.

Q. That is not a generic company, is it? A. No.

Q. What other Dexamethasones do you stock? A. Hexadrol.

Q. Just tell me the company? A. Organon.

Q. Organon sells it under its brand name, doesn't it? They don't sell it under the generic name? A. That is correct.

* * *

[Tr. 327] Q. Let me ask you another question. How long have you been a pharmacist? A. 24 years.

Q. For these 24 years has not the prevailing practice been for generic companies to have look alike drugs? A. Yes.

* * *

Q. In your pharmacy, does the price of a prescription drug that you charge to a customer vary in relationship to the cost of the drug to you? [Tr. 328] A. Yes it does.

Q. Is it a direct relationship? A. Yes.

Q. Does the New York State Pharmaceutical Society play any role in enforcing the rules or ethical precepts with respect to

pharmacists if they do something that is unethical or illegal? A. No, sir.

Q. So there is no equivalent of the Grievance Committee of the Bar Association in this Pharmaceutical Association, is that correct? A. That is correct.

Q. How many pharmacists are there in New York State? A. 15,000?

Q. How long have you been the president of this association? A. Seven months.

Q. Have you been a member of the Association prior to your being president, I assume you have? A. Yes.

Q. For how long? A. Ten years or maybe more, perhaps 14 years.

Q. Do most of these 15,000 pharmacists belong to [Tr. 329] the Association? A. No, sir.

Q. How many do? A. 2500.

Q. If a pharmacists [sic] is charged with doing something unethical or illegal, where is that charge made against him? A. The State Board of Pharmacy.

Q. Do you know how many charges concerning illegal substitution of one drug for another were made in the past year against a pharmacists? A. I have no knowledge of that at all.

* * *

Excerpts of Trial Proceedings

Q. Mr. Lawlor, in your pharmacy how do you stock your products? A. I don't understand the question.

Q. Do you stock them by brand name? Do you stock them by alphabetical order? A. Alphabetical order.

Q. Now, when you get a prescription for a drug product, what is your general procedure in filling it? A. Well, I ascertain that the patient's name is [Tr. 330] on the prescription and that is correct.

The patient's age.

I examine the prescription of what it says and get the patient's records out.

I type the prescription label.

Get the pharmaceutical out.

Package it.

Label it.

Deliver it back to the patient and discuss the medication as to the condition with the patient.

Q. Now, when you get the pharmaceutical out how do you ascertain whether that is the correct pharmaceutical for what is prescribed? A. Well, I go to the drawer where it is supposed to be and I get the bottle.

And I am a pharmacist and I know the name of the drug, the generic name of the drug, and the strength.

Q. Do you look at the label on the bottle? A. Yes.

Q. You check that with the description? A. Yes, that is correct.

Q. Now, I will show you a bottle marked Exhibit 9 for Inwood.

THE COURT: Defendant Inwood's Exhibit 9.

[Tr. 331] Q. (Continuing) And a bottle — this is a container, and the box has been marked Plaintiff's Exhibit 6, and it contains a bottle inside —

MR. TROST: We marked this as Defendant's Exhibit 9A since this bottle is not marked.

Q. (Continuing) Now, if the patient comes in with the prescription that says Cyclospasmol on it what would you then do? A. I would go to the location in the pharmacy that Cyclospasmol is located, get the bottle and fill the prescription.

Q. Would you check that the Cyclospasmol, in filling it where it is labeled with — Ives' product? A. Well, if I am looking for Cyclospasmol it has to be Ives' product.

Q. And would you innocently confuse this bottle, which is 9A, with this bottle, Exhibit 9, which is labeled Inwood cyclandelate? A. Would I confuse them? No.

THE COURT: Which is the cyclandelate? The Inwood, is it not?

Excerpts of Trial Proceedings

MR. TROST: Inwood Exhibit 9, your Honor.

THE COURT: And the other is Ives, I take it.

MR. TROST: We will mark it Inwood 9A.

[Tr. 332] Q. Now, after you get the bottle from the shelf, what do you then do? A. Count the required number of capsules and place them in my prescription bottle with my label on it, and dispense it to the patient.

Q. All right. Could you open up 9A and just pull a couple of capsules out.

(Witness complies.)

Q. Now, seeing those capsules you also check as to if there is any logo on the capsule? A. Only incidentally. If I have the bottle with them I know it is from that bottle.

Q. What would that logo tell you looking at it? A. That these are Ives, and the product number on it, which is they are identical.

Q. Now, could you open up Exhibit 9?

(Witness complies.)

Q. What does Exhibit 9 say on it? A. It says Inwood 258.

Q. And would you as a pharmacist innocently confuse that product which is labeled Inwood with the other product labeled Ives in filling the prescription? A. Not if I only had this bottle.

Q. You would confuse it? [Tr. 333] A. I would not confuse it.

Q. Has anyone at the Inwood Laboratories ever suggested to you that you should illegally substitute this product for Ives' product? A. No.

Q. Do you know offhand from what generic companies you have products stocked?

We are talking about companies that do not detail? A. I have some products by Zenith. I have some products by Spencer Mead.

Q. Do you know offhand any of the names?

THE COURT: Names of the product?

MR. TROST: Yes, names of the products. A. Spencer Mead, I guess it is their tetracycline that I have. I have folic acid from them.

THE COURT: What is that?

THE WITNESS: Cortisone.

A. (Continuing) Zenith I have their chlordiaz — epoxide.

I have Zenith's Dithenhydramine.

* * *

Excerpts of Trial Proceedings

[Tr. 352] THE COURT: With respect to that particular drug, do you know of any instances where a drug has been illegally, so to speak, substituted a generic for a brand name?

[Tr. 353] THE WITNESS: I know of none.

THE COURT: Would it be your judgment that that is a wide spread practice among pharmacies?

THE WITNESS: I don't believe it to be wide spread, no, sir.

THE COURT: Now, in those cases where you may have forgotten there aren't any — if there aren't, tell me — but if there are cases where initially you don't explain to the customers, "Look, this is a different color, but it's the same drug as you have been getting before, has there been any such instances?

THE WITNESS: Where we have neglected to tell them there has been a color change?

THE COURT: Yes.

THE WITNESS: Yes, sir.

THE COURT: Can you tell us in those instances, if you can, what percentage of those people come back and ask you about it or question it?

THE WITNESS: I would say if we haven't explained that there is a difference generally there is a question as to why the color is different?

THE COURT: They'll ask you —

THE WITNESS: Why the color is different or [Tr. 354] whatever appearance it has.

* * *

[Price, Tr. 356] Q. Mr. Price, where do you reside? A. Nassau County, Seaford, New York.

Q. What is your occupation? A. I am a registered pharmacist. I am Director of Pharmacy at Nassau County Medical Center.

Q. Are you licensed to practice pharmacy in the State of New York? A. Yes, I am.

Q. For how long —

THE COURT: How long have you been at Nassau County Medical Center?

THE WITNESS: I started there in 1966 and I became director in '69.

Q. Before your tenure at Nassau County Medical Center, Mr. Price, did you practice pharmacy in New York? [Tr. 357] A. Yes, I did.

* * *

[Tr. 358] You order specific drugs from the Bureau of [Tr. 359] Purchases — you place orders and say, "I want to buy x

drugs"? A. Basically that is one of the things. We let them know what our needs are. They establish a vendor at a price, and then we draw off the contract.

Q. Now, when the bureau purchased — buys a particular drugs [sic] pursuant to this competitive bidding system, what are the criteria by which a bid is awarded on a — when a supply contract would be awarded to a vendor? A. Again, it is competitive bid and it is on a generic basis.

Q. When you say "competitive," do you mean the lowest bidder gets the contract? A. It may not necessarily be true that the lowest bidder gets the contract for a specific drug. I don't know what formula they use. There are times that they may allocate one vendor — we get a catalogue price. They make the decision. I don't know. I am not party to it.

THE COURT: The lowest responsible bidder?

THE WITNESS: That is true.

Q. Is the color of a particular drug a part of the specifications for drugs that are to be purchased by the Bureau of Purchases? A. Color is not.

[Tr. 360] Q. You mentioned that the drugs are on a generic basis.

Does that mean when you order a drug from the Bureau of Purchase you order it by the generic name? A. Yes, it is the generic name.

Q. What is the typical term of a supply contract for a particular drug — for how long would this company — A. You mean the contract period?

Q. Yeah. A. Generally about a year.

Q. During your tenure as Director of Pharmacy at the Medical Center in Nassau, have supply contracts for the same prescription drug been awarded to different vendors in different years? A. Yes.

Q. Has this practice ever resulted in a change of the color of the dosage form of a given drug dispensed by your pharmacy? A. Yes, it has.

Q. How often has it occurred? A. Could be on an annual basis.

Q. Frequently? A. Yes.

[Tr. 361] Q. What is the reason for such a change in color? A. Change in brand — change in the supplier.

Q. Would you be able to give the Court examples of drugs made in different colors by different manufacturers or vendors, if you will, that have been purchased by the Bureau of Purchase and dispensed by your pharmacy over the past several years? A. Ampicillin, we have purchased from Bristol Labs as Polycillin, as a red and gray capsule. We now purchase it from Bristol as a white and brown capsule in addition.

Penbritin which is Ayerst, red and black and Principen rom Squibb which is I'd say, sort of a lavender.

Eftextracyclin from Leatherly [sic, Lederle] as a blue and yellow capsule, Sumycin from Squibb. That is a pink capsule.

We have purchased isosorbide from Stewart as sorbitrate, that's the two and a half milligrams on sublingual tablet, that is white. A five milligram sublingual is pink. The ten milligram oral is yellow.

We have purchased Ives' brand of Isordil, two and a half milligram is yellow, five milligram is pink, the ten milligram oral tablet was white.

We have purchased chlordizepoxide from —

[Tr. 362] THE COURT: Do we need all these, Mr. Raubicheck? I'll listen to them if we need them.

MR. RAUBICHECK: I believe, your Honor, Mr. Price has indicated a substantial knowledge of drugs —

THE COURT: Fine, if you want me to listen, I will listen.

MR. RAUBICHECK: He in this connection, I believe, has prepared a list of such drugs in different colors. We could have him identify it.

THE COURT: He could have gotten through them by now. Go ahead. A. Chlordiazepoxide Squibb Noctec is an orange-red and we have purchased the same product or generic product from American Cyanimide as a green capsule.

Purchased ampicillin fromMerck, Sharpe Dome as Elavil. Ten milligram blue, 25 milligram yellow, 50 milligram brown, 100 milligram lavender.

We also used Hoffman-LaRoche's 10, 25, 50 is an orange, 75 is yellow, 100 milligrams is brown.

There are more, but I don't know how many more you want.

MR. RAUBICHECK: Thank you, Mr. Price.

[Tr. 363] Q. From your experience at Nassau Medical Center, has the dispensing by your pharmacy of the same prescription drug in a different color at a different period of time caused any resistance, to your own knowledge, from in-patients at the hospital? A. No.

Q. Have doctors indicated any resistance for prescribing different colors? A. They don't prescribe by color.

Q. How do they prescribe? A. They prescribe basically by generic name.

Q. What about nurses, have nurses come to you and expressed a resistance to — administer to in-patients drugs of different colors? A. As long as the material is properly identified, the nurse will administer the drug regardless of color.

Q. When you practiced — practice pharmacy before you came to Nassau Medical Center, did you ever dispense to a customer the same drug in a different color from the drug that the patient had been taking previously? A. Yes.

Q. And did you ever receive any inquiry from such a patient about the change in color? A. No. Normally if I was going to change the [Tr. 364] brand of an item for whatever

reason was necessary, I would inform the patient, so that they were aware that a change was taking place.

Q. And in any of these instances, did a customer refuse to accept the medication? A. None.

Q. Based upon your professional experience in the field of pharmacy, Mr. Price, do you have an opinion on the question of whether drugs which are marketed under their generic name should be made in the same color and appearance as the same drug which is marketed under a brand name? A. No, they don't necessarily have to be the same color.

Q. And what are your reasons for this opinion? A. Well, one is personal, more or less. The fact that it can stand as a quality control test.

Q. Could you explain that? A. It is very simple. There are sometimes when you're talking to a patient and they say to you, gee, you know, the last batch of red tablets you gave me weren't quite as good as the green batch. It kind of alerts you to the fact that you may have a problem on your hands. It is something that you just can't tell by looking at it. It is [Tr. 364A] something that has to be taken internally, you know, and you get the response.

* * *

[Kittelberger, Tr. 378] Q. Would you take a look for a moment at these documents that were in the envelope, in Exhibits 82, 000, and turning your attention to this first document that you have in your hand, could you identify that for the record? A. This is a photocopy of the prescription which I presented to the Frankel (ph) pharmacy.

Q. And — Go on. A. On it he had go of it I identified it after leaving the pharmacy with the prescription, with the date, the name of the pharmacy, the price that I paid for the prescription and my signature.

Q. And were you instructed to make those notations on the copy of the prescription by Mr. Adler? A. I was.

Q. And what is this second document containted [Tr. 379] in the Exhibit? A. The second document is a stapled receipt, a receipt with, two receipts, I should say, one is a registered receipt and the other is a written receipt from the same pharmacy showing what I paid and also identified.

In one case it's just my name and date because the address was on the other side, on the register tape is the name and address of the drug store.

Q. Were you instructed to make those notations by Mr. Adler? A. I was.

Q. Could you identify this object that was within the envelope? A. This appears to be the prescription that I left on that date, because it has my initials, the date and I taped it on to the container when I left.

Q. When you say prescription, prescription bottle that you received from the pharmacy? A. Yes.

Q. Did Mr. Adler instruct you to make those notations on that tape? A. Yes.

Excerpts of Trial Proceedings

Q. Now, Mr. Kittelberger, after you made the [Tr. 380] purchase, did you then place the prescription bottle in that manilla envelope? A. Yes, sir.

Q. That you have in front of you? A. Yes, sir.

Q. And did you make any notations on this envelope? A. Well, before I put it in the envelope, I would have to write on it, because of the fact that once it's in there, you couldn't write on it.

So before I sealed everything, I would seal then, I would write my report and identify it.

Q. Is that your writing on the outside of that envelope? A. Yes.

Q. Is that your signature on the bottom? A. Yes.

Q. Now, I take it that after you completed the transactions and wrote out your report, you placed the bottle and the copy of the prescription and the receipt from the pharmacy in the envelope, is that correct? A. Yes, sir.

Q. Now, what did you do with the envelope and its contents after that? [Tr. 381] A. I sealed it, and usually, if — on this particular day, I had other shoppings to and I kept it in my locked car until I returned home and I am not sure if I went to Mr. Adler that evening. I believe it was a day or two later that I brought all the prescriptions to him.

Q. Now, with respect to this particular exhibit, 82, 000, did you ever, you personally, ever open that prescription bottle from

the time you received it from the pharmacy to the time you delivered it to Mr. Adler? A. No, sir.

Q. To your knowledge, did anybody else ever open the bottle? A. No, sir.

Q. Is it your testimony that this package and its contents remained in your custody during that whole period of time until you delivered it to Mr. Adler? A. Yes, sir.

* * *

[Lehmann, Tr. 399] Q. Were you a pioneer, sir, in the use of such [Tr. 400] drugs in the treatment of psychiatry in North American? A. I think one could say that because I introduced the first major tranquilizer or anti-psychotic drug and I was the first one to bring the anti-depressant imipramine or the first major anti-depressant into North America from Europe.

Q. I also notice that you hold the position of Director of Research of the State of New York Office of Mental Health.

What does that entail on your part, please? A. It entails coming to New York or Albany or both places about once a week for a day or two, and helping the — assisting the Deputy Commissioner for research in the mental health department for the State of New York with administering the research operation of the state.

There are three research institutions, state supported, and the administration of these three institutes and research, in general, is rather complex.

And I assist the Deputy Commissioner and the Commissioner of Mental Health in the running of this.

Q. What is the Royal Society of Canada of which you are a Fellow? A. The Royal Society of Canada is parallel to the British Royal Society. It is a community of researchers [Tr. 401] where one can only enter upon invitation by your peers. So it is an honor to be invited or to become a member — to be nominated a member of such a society.

To my knowledge I am the first psychiatrist to be elected to the Society. They have all kinds of scientists, astronomers, mathematicians, physicians, but I don't think any psychiatrists.

Q. Now, in your personal experience in connection with the treatment of patients over the years, has there ever been an occasion, to your memory, where you prescribed to a patient the same drug of the same dosage form, but it was a different color because it came from a different manufacturer? A. Yes. I remember several instances and two or three drugs where that happened.

Q. What were the drugs, sir? A. One was diazepam where it happened most frequently. The brand name is Valium made by Hoffman-LaRoche and I often prescribed — usually prescribe now the name Vivol, which is the name of diazepam, but made by another Canadian firm and it is green while Valium is yellow.

It is also a brand name Vivol but I think they have a license from Hoffman-LaRoche who make Valium and like generic drugs it is cheaper than the Hoffman-LaRoche. It [Tr. 402] looks different, but it is the same substance.

Q. In addition to Valium, has there been any other drugs where you recall having changed the color? A. Yes, Stelazine which is a brand name for trifluoperazine Hcl. It's originally made by Smith, Kline and French. They're now — it is under the name of Solium in Canada. It is made by Honer and by a British firm under another name.

I have prescribed solely Valium instead of stelazine.

Another drug is amitriptyline which is Elavil. The brand name is Elavil by Merk Sharpe and Dome and I have prescribed it under the name of Deprex, which is made by a British firm, Beecham Product, and it looks different, but it is the same substance.

Q. Now, I will refer you to the brand names because I can't pronounce the generic names.

What kind of drug is Valium? A. It is a so-called minor tranquilizer or anti-anxiety drug.

Q. What is Stelazine? A. An anti-psychotic drug against major illnesses.

Q. What is Elavil? A. It is an anti-depressant.

[Tr. 403] Q. In connection with this change of color, has any patient refused to take the medication because the color was changed? A. No.

Q. Has any — did any of your patients have an anxiety reaction as a result of the color change? A. No.

Excerpts of Trial Proceedings

Q. Did you observe in any instance that the drug with the changed color did not seem to be working as well on the patients? A. No.

Q. Now, do you know what kind of product is involved in this suit you're testifying in? A. Yes, cyclandelate or Cyclospasmol.

Q. What kind of product is that? A. It is a vasodilator.

Q. Do you have an opinion as to whether or not a patient on a vasodilator would be more likely to be anxious and upset over a change in color as opposed to the patients you spoke about who are on the anti-depressant and schizophrenic drugs?

* * *

A. I don't think so. I cannot acknowledge why [Tr. 404] there should be a difference.

Q. Do you ever treat elderly patients? A. Yes.

Q. Have you also treated younger patients? A. Oh, yes.

Q. Has it been your experience that the elderly patients seem to have more confidence in their physicians than younger people do? A. In general, yes. They're easier patients. They have more faith in authority as a rule than the younger patients particularly the very young adults who have a general distrust in authority and therefore keep shopping around and criticizing and trying to tell the doctor what to do and so on.

* * *

Q. Do you have an opinion, Dr. Lehmann, as to whether it is medically necessary for the same drug in the same dosage form to also be in the same color? A. Medically necessary, I don't think so.

* * *

[Tr. 414] Q. Would you describe what a placebo effect is? A. It's a psychological effect of a drug which is not — for which there is no pharmacological basis.

If somebody is given sugar in a gelatin capsule and told it's an active drug against headaches, and if he has a headache and he takes the sugar capsule and the headaches disappears, it's not a pharmacological but a placebo effect.

Q. Is it sometimes usefull to change the appearance of a drug that a patient is taking in order to induce a placebo effect?

For example, in a patient with a psychosymatic [sic] illness, if a drug is given such as aspirin, and if the patient thinks it's not working, is it sometimes useful to give the patient the same drug in a different color and [Tr. 415] in that way try to induce a placebo effect? A. It may work.

THE COURT: This is a real effect, the placebo effect?

THE WITNESS: A very powerful effect. It may be a more powerful effect then the pharmacological effect.

It's unpredictable even in the same person.

One day they may react to it, the next day they may not.

Q. Every so often patients that you have seen who have cerebral arteriosclerosis also suffer from other diseases in addition to that? A. Yes.

Q. Do some of these patients see a number of doctors, perhaps one for psychiatric problems and one for a physical problem? A. Yes.

Q. In some cases do the different doctors each prescribe the — a different drug for the patient, depending upon the specialty and the malady? A. Yes.

Q. Are some of these arteriosclerotic patient [Tr. 416] who are on different medications, self-medicating take the drugs at home by themselves? A. Yes.

* * *

[Getson, Tr. 432] Q. Based upon your professional experience and training, Doctor, will a responsible emergency room physician ever attempt to make a positive identification of an overdosed drug based upon color and appearance alone? A. No.

Q. Based upon your experience, will such an emergency room physician attempt to make a positive identification by reference to the product identification section of the Physician's Desk Reference? A. No.

Q. What reasons do you give for that last statement? A. The Physician's Desk Reference, if I can use the abbreviation PDR?

Q. Yes. A. Is a descriptive guideline publication that physicians use for that alone. In the emergency room situation [Tr. 433] we cannot rely on that because the colors of the medication as identified in the PDR are usually not accurate. In fact, I believe that is stated in the beginning of the PDR's identification section.

Another problem with using a color match up situation there are — there are several prescription drugs that look alike and are indeed at opposite ends of a chemical spectrum which would lead one to disastrous end if he tried to treat a patient specifically when you're dealing with another medication.

The third aspect of that, there are many over the counter drugs. In fact, some of them are frequently abused that are identical to the drugs that appear in the PDR.

Q. By what? A. By appearance, color, shape.

Q. In that regard, Doctor, I would like to show you a document, after showing it to counsel, which has been marked Plaintiff's Exhibit 114 for identification, and ask you if you have ever seen this document before? A. Yes, I have.

Q. Would you identify it for the record? A. It is — entitled, "Drug Abuse, a Manual for Law Enforcement Officers."

[Tr. 434] Q. Who published it? A. The Smith Klein French Labs in Philadelphia.

Q. I call your attention to the fold-out on page 46 of the document, and I ask you if you have seen that before? A. Yes.

Q. Could you identify it for the record? A. This is as they describe it, the non-prescription medication describing and showing — showing the prescribed drug next to the over the counter drug, and this is — they list amphetamines in one column and barbituates in another.

Q. What is the point of that fold-out? What point does the publication try to make? A. They show clearly that identification of medication purely by appearance is impossible.

Q. Dr. Getson, if an emergency room physician were to attempt to make a positive identification of an overdosed drug based solely on color and appearance, do you have an opinion based upon your professional training and experience as to whether or not this will be potentially harmful to an overdosed victim? A. Yes, this could be disastrously harmful.

* * *

[Tr. 439] Q. Did you file an affidavit in this case? A. Yes, sir, I believe I did.

Q. Have you reviewed it recently? A. Yes.

Q. You stand by what it says? [Tr. 440] A. Yes, I do.

Q. Would you refer to paragraph five, please. (Document shown to the witness.) A. Yes.

Q. I want to read to you the section on the dispensed prescription bottles not available.

"The physician will ask a family member or a friend or a relationship as to the overdosed drug could be found. They

would give him an oral description of the appearance of the drug."

When you made that statement, what did you intend that they do with the information relating to the oral description of the drug? A. Very often people identify a drug not only by color or shape, but by identifying marks and numbers, and very often I have had people tell me that they take a white pill with a four on it, certain identifying characteristics.

* * *

[Tr. 441] Q. Could you turn to paragraph c.

"In those instances where the attending emergency physician knows the pharmacist who dispensed the overdosed drug he'll contact the pharmacist for correlation for the color and appearance of the drug with the pharmacist's patient profile records."

That is your statement? A. Correct.

Q. Isn't it a factor here where they use the color as some sort of aid? A. If the color and appearance of the drug is in some way able to help the pharmacist in describing — in prescribing — in identifying what kind of medication was dispensed in a chemical since that is helpful for the pharmacist. In a therapeutic sense it has no bearing on the treatment of the patient.

THE COURT: I don't understand that. Explain it to me. That will be helpful to the pharmacist in finding out which drug it was?

Excerpts of Trial Proceedings

THE WITNESS: Well, your Honor, as you know [Tr. 442] there are many drugs that are prescribed and dispensed that are of various colors with a similar chemical composition.

Sometimes — I am speaking as a physician and not a pharmacist — sometimes in my experience a pharmacist can, with guidelines, look up his records and find out what a patient was prescribed.

THE COURT: And the color might be a part of the aid which would help him do that?

THE WITNESS: As described to me by a pharmacist, yes.

* * *

[Tr. 443] Q. Do you know what color Dilantin is? A. Yes, white capsule with a red strip.

Q. Librium? A. I believe it is various strengths in several colors.

* * *

[Sorenson, Tr. 507] Q. Just so that I know what you are saying no to; or what you are saying you gave some consideration to, how would you have gone about finding 100,000 estimated users of cyclospasmol in the entire country other than by using the means that Dr. Lipstein used?

What would you have done? A. Well, as I told you I have not made a thorough going definitive effort to determine how I would have done, since I had not been commissioned to do so.

I did, in responding to his Honor's question or perhaps remarks, did comment that there were other wasy [sic] that at least it occurred to me.—

One would have involved a screening process that indeed would have been time-consuming and costly.

[Tr. 508] Q. And who would you have screened? A. I would have screened individuals who could be contacted for instance by telephoen [sic] on a random probability basis thorughout [sic] the country.

Q. Any other ways occur to you? A. At the moment, no. But I would be happy to give it further thought.

Q. Now, how would you have gone about finding the appropriate universe if you were asked to find prescribers of cyclospasmol? A. This does not deal with my testimony, but I guess that does not matter.

THE COURT: No.

Answer the question.

I listen carefully to your testimony.—

THE WITNESS: All right.

There are one of two ways basically of securing the names of physicians who have prescribed cyclospasmol.

One is to go through the detail men that your survey organization did. The other would be to secure as exhausgive

[sic] a list of physicians as possible, perhaps confining them to certain categories of physicians, and then to screen those [Tr. 509] individuals by telephone or by letter or a combination of telephone and personal visit for their use of Cyclospasmol.

* * *

[Tr. 559] Q. What do you think is a good response in a situation like that?

* * *

THE WITNESS: The problem is that a good response rate is not necessarily the best you can get. At the same time we know that some response rates are unrealistic to anticipate. I have no answer. I know that response rates are difficult with physicians. There's no doubt about it.

* * *

[Tr. 560] Q. Dr. Sorensen, assuming for purposes of this question that there are approximately 100,000 persons in the United States for whom cyclospasmol has been prescribed at one point or another, do you have any opinion, based [Tr. 561] on your experience, as to how many households would have to have been telephoned in order to get a representative response? I believe telephoning was one of the ways you suggested we could reach patients. Q. Well, that — one could certainly develop a rough calculation. Assuming that there are approximately 68 million households — not knowing the correlation between telephone ownership and the prescription or the recipients, if you will, consultation of cyclospasmol, but assuming for this rough movement that there is approximately equal

correspondence, it would mean obviously, dividing 65 million by 100,000, that would represent an obviously very, very large number.

Q. Would it have been extraordinarily expensive? Would it not? A. It would have been extraordinarily expensive.

Q. And time consuming? A. Correct.

Q. Now you indicated this morning that you had reviewed the questionnaires and that in four instances you noticed that the word "cyclospasmol" had been misspelled. A. Yes.

* * *

[Tr. 566] THE COURT:

* * *

They have been getting cyclospasmol and it has come in the blue tablet.

THE WITNESS: Yes.

THE COURT: And the pharmacist substitutes a different capsule, not tablet, capsule.

THE WITNESS: Yes.

THE COURT: And let's assume for the moment now that it's perfectly proper for him to do that because the physician has signed under substitutions permitted, and then they get a different color, but it's the same generic product. Could you

design a survey to see which one of — what number of those people would be likely to raise a question or refuse to take it or raise a question with their physicians? Or would that be so hypothetical that it wouldn't be worthwhile?

In other words, one of the question I have to decide is to what extent would someone, if they saw a different color, raise a question with their pharmacists or doctors that they are not getting the same thing, and that it wouldn't have theraputically the same effect?

THE WITNESS: I think such a survey could be [Tr. 567] designed. I think that how passive it would be would be another question. But it's possible to design a survey where — and I am really giving you a very off the cuff reaction, that would involve the cooperation of a certain number of doctors and certain number of pharmacists.

The problem is that no doctor, or few doctors willingly call their judgment into question on the part of a patient. So if a patient — a doctor were worried about whether a patient believed there was a question with respect to the ingredients or the theraputic value, then the doctor might not want to cooperate in such a real life survey.

THE COURT: Let me ask you another question. Let's assume there are a great number of pharmacists out there who are not following the physicians orders, and where the physician puts down, dispense as written, signs on that line, as opposed to substitution permitted, in fact, in order to make an extra dollar or two he substitutes the generic drug, where the physician has told him not do [sic], and he gives him the same or what looks like the same blue capsule.

Would it be possible to take a survey to see how widespread that was?

[Tr. 568] Now, bear in mind in New York State they are violating the law, and maybe in some other states.

Take New York, for example, would that be possible to survey?

THE WITNESS: Yes.

* * *

[Taylor, Tr. 574] Q. Have you ever prescribed cyclospasmol or cyclandelate? A. No.

Q. Can you explain why not? A. I didn't think it helped.

Q. In your private and clinical practices have you [Tr. 575] ever treated a patient who was taking more than one medication? A. Yes.

Q. Why is that so? A. Well, very frequently a patient will have more than one disorder and so he would have to be given medication to handle the variety of symptoms.

Q. Is this particularly true of patients with nervous disorders or elderly patients?

THE COURT: That's two separate questions, isn't it?

MR. MARROW: Yes, I will separate them.

THE COURT: What can you say about elderly patients in that regard?

THE WITNESS: In general elderly patients tend to have more than one disgnosis and, therefore, tend to be placed on more than one medication.

THE COURT: How about those with nervous disorders?

THE WITNESS: They may have more than one, but it's not a given.

Q. Now, these patients who were taking more than one medication, were any of those suffering from senile dementia? A. I am sure some of them were, yes.

[Tr. 576] Q. And were some of those suffering from senile dementia and taking more than one medication self-

medicating? A. If you mean by that that they were responsible to take their own pills, yes.

THE COURT: They take them at home, for example? A. Yes, they are responsible for the pills.

Q. Do you consider this a safe medical practice if a patient is disoriented, forgetful, et cetera? A. No.

Q. Did you continance or permit it? A. Very often you have no choice. If the patient lives alone and has no relative or close neighbor who would be responsible, you are stuck.

Q. Are there also degrees of senile dementia where it might be safe medical practice to permit self-medication? A. Yes, there are some patients who have it in mild form. Others are so severely disabled that you couldn't begin to let them do it.

Q. Now, would you say that there is such a danger that such a patient might take a medication on the wrong schedule? A. Yes.

Q. Do you recall any specific instances of that [Tr. 577] happening in your own practices? A. I can't recall of a specific instance, no.

Q. If such a thing were to happen would it create a danger to the patient? A. It certainly could.

Q. Are you familiar with any medical studies of patient compliance with instructions for taking prescription drugs? A. I am aware that many such studies have been done, yes.

Q. Is there a relative uniformity in their results? A. Yes. In general they have shown the patients not to take the pills as they have been directed.

Q. Have you ever treated a patient who kept more than one medication in the same bottle or pill box? A. Yes.

Q. Was this a common practice or an usual practice? A. Very common.

Q. Did you have a practice that you utilized in order to minimize the possibility of the self-medicating patient taking the wrong pill on the wrong schedule? A. I would sometimes try to suggest that they start [Tr. 578] in the morning and take out whatever pills are needed in the day from different bottles or sources, and then note that for that day they have perhaps four or five pills to take, and segregate those pills perhaps separately in another container; and hope in that way they would be at least correct for the day.

Q. Did you ever do anything to aid the patient aside from giving oral instructions regarding taking medication? A. I would very frequently write out a schedule as clearly as I could so they could pin it up somewhere.

Q. In your opinion do patients associate the color of medication with any particular aspect of taking that medication? A. Yes.

Q. And how does that come about? A. Well, they will say, "Oh, the red one is my heart pill," or something like that.

Q. Did you ever use the color of a pill in the course of your practice to aid the patient in identifying a schedule to take it? A. Yes, I did.

A. And how would you do that? A. Just as I said before. If he knew that the red [Tr. 579] pill was for the heart pill or the blue bill was the nerve pill, it would be helpful to me to be able to say, well, you are supposed to take the blue pill three times a day, or what have you.

Q. What is a maintenance drug, Doctor? A. It is a drug which the patient usually takes everyday in an effort to control certain symtoms, [sic] although one knows they may not secured by that means.

THE COURT: Over any particular period of time?

THE WITNESS: Yes. It could be any period of time.

Q. Well, if you are describing something as a maintenance drug, would that definition imply any certain extended period of time, or what? A. It certainly implies an extended period.

Q. Have you ever prescribed maintenance drugs in your practice? A. Yes.

Q. In your opinion do patients become accustomed to the appearance of such drugs? A. Yes, they do.

Q. Are maintenance drugs more generally taken by elderly patients than in young patients? A. In general, yes.

Excerpts of Trial Proceedings

[Tr. 580] Q. In general, can you explain that. A. Since elderly people are prone to chronic diseases in which a maintenance drug is the only way of offerring them any help.

Q. In your experience, have elderly patients been more or less concerned about the price of drugs than younger patients? A. Elderly patients usually live on very restrictive income and are worried about the price.

Q. In your experience are elderly patients frequently concerned with the convenience of obtaining drugs, for example, from a nearby pharmacy? A. Yes, indeed.

Q. In your opinion, do patients rely upon the appearance of a drug product to insure themselves that they are receiving the proper medication? A. Yes they do frequently.

Q. And what is the basis of your opinion? A. The things that patients have said to me.

Q. Have you ever had the experience of treating a patient or a group of patients who continued to take the same drug in the same dosage form, but with differring [sic] appearance? A. Yes, I have.

[Tr. 581] Q. Could you explain to the Court the nature of your experience in that regard. A. Well, several years ago, I forget if it is eight or nine, maybe 10 now, a new drug came out for the treatment of Parkinson's disease, which is commonly known as L-D-O-P-A. It is an acronym.

Q. Do you know the actual name of the drug?

THE COURT: You don't need it. We all know Ldopa now. A. Originally when it came out it was made by a company, I forget who made it but it was very expensive. Patients were anxious to get it and they would pay I think between 50 and 75 cents a pill.

Q. For each pill? A. Yes.

Q. What did the pill look like? A. They were white and elongated.

Q. Was it a tablet or capsule? A. It was a tablet.

Q. Continue. A. And then a year or two later a short time later the patent elapsed and several other manufacturers began to make it. And also at the same time a process was discovered by which it could be made far more cheaply from [Tr. 582] vegetable plant sources rather than anomal sources, so that the price dropped. And from 60 or 75 cents, it was about 5 or 7 cents per tablet.

Then each of these manufacturers put it out under a brand name and everyone of the products had a different appearance.

Q. What was the patients' reaction? A. Frightened.

Q. I'm sorry? A. They were frightened. They didn't know it was the same drug because instead of being a white tablet, they were now getting pink capsules and green capsules and white round capsules, four or five different varieties and they had no way of knowing whether it was the same medication.

Q. Did they express their fright to you? A. Yes.

Q. Did you explain to them that the same drug was now being made in different appearances? A. Yes. I did try to explain it to them.

Q. What was the result of your explanation? A. Well, some patients accepted the explanation and they were glad that it was cheaper. And others did not feel happy with the explanation and elected to continue with the original drugs, if they could, although it was more [Tr. 583] expensive.

Q. Do you remember any specific instance of a patient going to great lengths to get the original product? A. Yes. I had one patient who was a retired dentist. And my practice was in Westchester County. When he originally started on the medicine I had him in the hospital in the Bronx. And he continued to drive down to the Bronx to fill his prescription, long after the substance was available more cheaply and in the neighborhood pharmacies.

Q. Doctor, have you ever had any emergency room experience? A. Yes.

Q. When was that? A. Intermittently, both while I was in training and, of course, while I was out in practice I would be called to emergency rooms.

Q. If a patient is brought into an emergency room suffering from an overdose of some drug, or whatever trauma it might be, is it important to identify the drug in the case of the overdose, or in the case of the trauma, whether the patient is taking a drug? A. Yes, it is very important.

Excerpts of Trial Proceedings

[Tr. 584] And is the color — is the color or appearance of a drug sometimes used as an aid in identification for the drug? A. Yes, it is.

Q. Would you explain how that takes place? A. There are some drugs which are available in standard preparation for so very long that just by looking at the outside one could be certain that it contains the same material.

Q. Would there be any other factors that you would take into consideration besides the appearance of the drug? A. Of course, if the patient could tell me what they were taking, it obviously would help.

Q. Anything else? A. Call their physicians if they had one.

Q. Do you recall — what drug are you talking about or drugs? A. Simplest thing that comes to my mind is dilantin which is in a white capsule with a red back since Park-Davis brought it out. If you see that you're not in much doubt.

* * *

[Tr. 585] Q. Based upon your experience, do you have an opinion whether it would be desirable for all drug entities which contain the same active ingredients and have similar pharmalogical properties to be the same shape and color? A. Yes, I do.

Q. What is that opinion? A. I think that would be a very good idea for them all to be the same.

Excerpts of Trial Proceedings

Q. Could you explain why? A. Because of the problem of knowing what is inside the drug, what is inside the tablet, there would be much less question in a confusing situation.

[Tr. 586] Q. Dr. Taylor, you stated that you changed your career in 1977 from private practice.

What did you change it to in 1977? A. I went into research and health care services.

Q. Can you describe what your work has been from 1977 until the time that you became associated with New York Health and Hospital Corporation? A. I spent six months at the Institute for Health Care Studies with the United Hospital Fund and then went to work for the federal government in what used to be called HEW in the Health Care Finance Administration Office of Research.

Q. Then you came to the Health and Hospital Corporation? A. Yes.

Q. Have you seen any private patients since 1977? A. No, I haven't.

Q. Have you treated any patients since 1977 private or otherwise? A. No.

* * *

[Tr. 589] Q. Did you ever prescribe librium? A. Yes.

Q. What is the generic name for librium, do you know? A. I am trying to remember. It escapes me.

Excerpts of Trial Proceedings

[Tr. 590] Q. Do you know whether librium — whether a product similar to librium with the same active ingredient is sold by various generic companies? A. I am certainly not sure.

Q. You don't know? A. I don't know — chlordiazepoxide —

Q. Chlordiazepoxide? A. Yes.

* * *

[Tr. 591] Q. What is elavil? A. Amitryptilene.

Q. What color is that? A. Yellow and blue.

Q. Have you ever prescribed amitryptilene to be prescribed as a generic? A. Yes.

Q. Do you know the colors? A. No.

Q. Why did you not see the capsules? A. Unless the patient brought them in and complained, it wouldn't be necessary to see them. If they brought them in to complain, then the whole subject would be raised.

Q. I assume no one ever did that with amitryptilene? A. Not to my recollection.

Q. Do you have anything to do with the purchasing of drugs by the New York City Health and Hospital [Tr. 592] Corporation? A. No.

Q. Do you know how the corporation, in fact, purchases drugs? A. Yes.

Q. How does it, in fact, purchase the drugs? A. The corporation has an office of procurements who are responsible for obtaining the best prices paid on contracts and that is a complex operation which I can't describe, but the responsibilities of that office is to insure that they get the best possible price for a contract for whatever drugs the corporation buys. Individual hospitals, pharmacies, are then informed through various mechanisms, clerical letters, if they wish to buy some drugs or other, the contract has been let with a particular company, at a particular price, and since that is frequently a more advantageous price, a large percentage of the corporation's drugs are brought through these contracts, but the ordering is done at the level of the individual hospitals and these are all generic.

Q. Do you know in issuing these contracts the corporation changes suppliers from time to time? A. They are obliged to go out on bid and naturally if the previous supplier doesn't meet the [Tr. 593] requirements and the bid comes in from someone else at a lower price, they would change.

Q. You're saying they would take the cheapest price they could get as long as there is not a quality problem? A. They have their own standards and qualifications which must be met.

Q. Do you know if the Health and Hospital Corporation requires that medication be in a particular color? A. I have never heard of that.

Excerpts of Trial Proceedings

Q. Now, I believe you stated in direct that you had had an experience with a color change in a drug for patients with Parkinson's disease? A. Yes.

Q. How many patients were involved? A. The change took place over the course of probably six months to a year and I saw several Parkinson patients every week, so I couldn't tell you precisely, but a fair number.

Q. When was that? A. This had to be in the early '70's.

Q. What are the symptoms of Parkinson's disease? A. The strongest symptom is a slowing down, [Tr. 594] inability to move properly, stiffness and difficulty in rising from position or change in position accompanied by a tremor and loss of capacity to demonstrate facial expression and there are others. Those are the common important ones.

Q. It is an extremely serious disease? A. Serious and disabling.

Q. Would you please tell us the extent of your emergency room experience? A. Well, during my training as a house officer there were regular rotation through the emergency room and of course I had four years of training. Then once I became a private practitioner I was on call to emergency rooms in hospitals where I had admitting privileges. So I was in and out of emergency rooms quite frequently.

Q. Could you tell us approximately how many instances — in how many instances you were present and called upon to treat a drug overdose in the emergency room? A. Yes, it would happen several times a year. I can't tell you exactly how many.

Excerpts of Trial Proceedings

Q. What would be the first thing that you would do when a patient with a suspected drug overdose came into the hospital? A. After I took care of the patient's acute problem —

[Tr. 595] Q. What would be the first thing you did when a patient came into the emergency room? A. Examine the patient and take a history, if possible, find out what needed to be done to them to turn this thing around.

Q. Would it be essential that if there has been a drug overdose that it — for example, the stomach of the patient be pumped out? A. The first thing you do is to make sure the respiration is protected.

Q. About when you're checking the respiration, do you happen to know what drug he supposedly overdosed on? A. Yes. Different drugs can have different effects on the respiration, certainly.

Q. How would you determine at that point if someone has been brought into the emergency room what drug they were on? A. Sometimes the clinical examination will reveal that by the nature of the respiratory change.

Q. Do you know, Dr. Taylor, whether a patient could be on an antibiotic and antihypertensive medication at the same time? A. Yes, they could.

Could a patient be on an antibiotic and [Tr. 596] analgesic at the same time? A. Yes.

Q. Could a patient be taking an antibiotic and a product for the symtomatic of cough and cold at the same time? A. Yes.

Q. Could a patient take at the same time two or more of the following antianginal, antihistamine, and a drug for Parkinson's disease? A. Yes, because very often Parkinson's patients responded well to antihistamines so that was included in their treatment.

Q. I show you what I have marked as Plaintiff's Exhibit 122 this morning, Dr. Taylor, and ask you if a patient brought this into you, how you would identify the medication the patient was taking?

(Exhibit shown to the witness.)

A. Just looking at this looks like cynamede.

Q. Which are you talking about? A. The blue oval.

Q. Do you think they're all the same? A. The color is slightly different. There is a larger and small one, the larger one is lighter, MSD-647, smaller — I am getting middle-age, I need glasses.

[Tr. 597] THE COURT: Do you want to try mine?

THE WITNESS: Thank you.

A. Says Stewart and it has no number on it.

Q. Would you rely on color to distinguish the medication that this patient has brought in — this hypothetical

patient? A. Color is very, very helpful, yes. For the rest I would have to rely on the name and their product, number —

Q. Why? A. Because I can't tell from what is in them. They could be anything. I would have to look them up. That would be true of all these that have names and numbers and I would go to the PDR in the product identification section.

* * *

[Tr. 599] Q. Are you aware, Dr. Taylor, that there are generic drugs on the market today that are not in the identical color of the drug first manufactured under patent? A. Yes.

Q. Do you know how frequently that situation, in fact, exists? A. No, I don't.

Q. Is it your testimony — your testimony was, I believe, that you didn't think it was a good idea to have the same drug in different colors; is that correct? A. No.

Q. This is your opinion, not a reflect of what actually exists in the marketplace; is that correct? A. Yes, my opinion is that the drugs should be the same color, right.

Q. Have you ever prescribed any kind of vasodilators. A. On occasion I used to prescribe some of the papaverine derivatives.

Q. Do you know which of the papaverine derivatives? A. That I prescribed generically, I don't remember the brand name.

Q. Do you know if it is available from several manufacturers in different colors? [Tr. 600] A. I don't know. I imagine it is, but I don't know.

* * *

[Gatty, Tr. 606] Q. Having reviewed those documents and exhibits 74 and 75, can you state your opinion as to whether it is possible to make a statistical meaningful projection to the population of doctors who prescribed cyclospasmol from the results of the survey? A. No, I don't think it is possible.

Q. Do you — could you state firstly in broad general terms without getting into details for each one, the reasons for your opinion? A. Well, the first one is the extremely low response rate.

Q. What is a response rate? A. Well, it is the percentage of people who have replied as a percentage of those one tried to contact.

Under probability sampling, when we select a target sample we are obliged to take interviews of those people designated, designated objectively.

A sample of successful completion is very low.

Q. What was the percentage of completion or reasponse [sic] rate in this case. [Tr. 607] A. I see it as 20 percent. I believe 169 out of 580.

* * *

Excerpts of Trial Proceedings

[Tr. 626] THE COURT: I see. How do you know that 80 percent of them will, unless you have gone through the whole process?

THE WITNESS: No, because theoretically we know from the normal curve —

THE COURT: Now tell us what that is.

THE WITNESS: It is one mathematical form of symetric bell curve in which suggests to us that these estimates will, most of them, fall in a distribution mainly about the true value, but we'll get some extremely high or extremely low.

THE COURT: Doesn't that depend upon the subject that you're after? The shape of the curve will that not depend upon what you're trying to find out and the subject matter that you're after?

THE WITNESS: No, your Honor. In general we find that the normal curve describes many natural phenomena. When it does not we can make [Tr. 627] mathematical transformation which will make it behave, so we can treat it in this way.

* * *

[Tr. 628] Q. Let me ask you a question. If you wanted to be right 80 percent of the time, what would happen to these confidence limits around the 24 percent and the 29 percent? A. If one is satisfied with 80 percent confidence one gets very wide — one gets reasonably narrow limits. If you make a more stringent requirement on the confidence what happens it becomes very wide.

Q. If you wanted to be right 95 percent of the time, you'd have to increase the limits around your result in order to encompass that 95 percent figure; is that correct? A. That is correct. I would look to the layman as if it were less accurate study. That is what we're getting from using an 80 percent confidence, in my opinion, a deceptive appearance of accuracy.

* * *

[Tr. 640] Q. Did you read the pharmacists — A. Yes.

Q. Do you have any comments as to that? A. First, the first impression I had was that it was sort of winged casually and I imagine that Dr. Lipstein was not called in until after it was done, because the — the using of two sources in the sampling —

Q. One was the Ives list and one was the Hayes list? A. Correct. — is most unusual. It really means to me that some non-professional began doing the study and — it was my impression that perhaps a professional was brought in, but I think what ought to have been done was to chuck out the first half of that and stick with the Hayes directory.

Q. Is there any justification of combining the two surveys, the Hayes directory pharmacists and those of the Ives list pharmacies? [Tr. 641] A. One has not detected a difference does not mean that a difference exists. Especially with much small samples where one is not likely to detect differences.

* * *

Q. What is the general practice in describing percentages to figures of this nature, Dr. Gatty? A. To start with I think it is not at all appropriate.

Q. Why? [Tr. 642] A. To use percentage figures when you have less than a base of 100. What we're talking about, for instance, four people here seem to be labeled 33 percent. That is, it seems to inflate it when you use two digits to represent a one digit number. So I would criticize that very sharply. It gives a false sense of accuracy which is not in the data.

Those percents are computed from the basis of subsamples and that seems in itself to be inflating of these percentages quite a bit.

For example, if we take on the last table of that report, the ten percent in the lower part of the table, cyclandelate dispensed and labled as cyclospasmol — it is ten people, that is given as 29 percent.

It seems to me much more appropriate to say that those ten people are taken out of 83 which is 12 percent. What we have is the figures engineered with their basis to inflate them in a way that could be misleading.

There are other points such as — which are perhaps minor that the two samples combined are inappropriate for another couple of points of view. One is that one of them is a simple random sample and the other is a cluster sample.

We have confused the precision of this. I [Tr. 643] think those are the main points.

* * *

[Sperber, Tr. 655] Q. When offering national-brand products for sale, what procedure have you followed as far as

describing the product, and please tell the court your reasons. A. You said when offering national brands?

Q. Yes. A. When we offer a national brand product we merely list it in a complete catalog with the name of the product, sometimes the name of the manufacturer and our [Tr. 656] selling price.

Q. Would you compare this with the technique you utilize when you offer a generic drug for sale? A. Yes.

When we offer a generic preparation, just the mere mention of the name of the generic name would be meaningless to many, many of our customers.

We therefore have to qualify that with a reference to the proprietary product.

In fact, within the last number of years the Food & Drug Administration has issued a regulation which requires all of the major brand manufacturers, including Ives, to list right on the label, and in all of their advertising to the profession.

And they even specify the size of the type, the actual generic name of the product.

And the reason this came about is because the population —

MS. DRISCOLL: I object for his giving reasons.

THE COURT: Is that in their report, what reason they gave?

THE WITNESS: I don't know if it is in their report.

But it is the reason we choose to market [Tr. 657] the product the way we do.

Why do you choose to market it that way?

THE WITNESS: Because the physician and the pharmacist, especially the ones that went to school when I did, 25 years ago, only know the product by the way in which the company details the product.

Ives does not use the name cyclandelate, they only use the name cyclospasmol.

Q. You made reference to the fact that you are referring a generic product to a branded product.

Is this what is known as comparative advertising? A. Yes, it is.

Q. Do generic drug companies detail their products? A. Do generic drug companies detail their product?

Q. Yes. A. No.

We generally are selling products at what we call generic price.

And we don't have the advertising budget allowances to be able to afford detailing our product.

Excerpts of Trial Proceedings

[Tr. 658] Q. Do you receive catalogs from generic drug manufacturers now as distinct from distributors who are offering their products for sale? A. Yes, we do.

Q. Generally do the generic drug manufacturers in their catalog use comparative drug advertising? A. Yes.

Q. And do you have an opinion what would happen if the generic drug manufacturers who offer their products for sale to you do not use comparative advertising with reference to the generic drug products they are offering for sale?

* * *

THE COURT: * * *

How do you define comparative advertising?

THE WITNESS: That is when I would take the generic name of the product and compare it to the branded product.

For example, we would in our catalog, we have a table where we would list the proprietary and national advertised brand on one side, and on the other side we would list the company brand [Tr. 659] product by its generic name or the name we sell it under.

THE COURT: What does a column with the generic name, what is it headed by?

THE WITNESS: Schein generic name or generic name.

THE COURT: Now, do you have an opinion on the question that was asked of you, suppose they didn't use comparative advertising?

THE WITNESS: Thank you.

Q. I am talking about generic drug companies who manufacture products which are offered to your company, the distributor. A. In my own personal case I am very much abreast of all the generic names.

I know for example though that many others in businesses akin to ours would not know what they are talking about unless they use the comparison.

* * *

[Tr. 664] Q. Mr. Sperber, in your opinion, would the pharmacist that receives your catalogues have any problem telling which is the generic product and which is the branded product?

* * *

A. The pharmacist for years has been detailed and sold the major brand products and he knows that dynoxin, the very first one, is a Leatherly product. He should have no problem identifying which is the generic and which is the branded.

THE COURT: Who determined these generic names?

THE WITNESS: That is part of the problem. The generic name is a name that is designated by [Tr. 665] some governmental body — scientific panel.

THE COURT: All right.

Do they make them up or is there some scientific — I suppose they must make them up like a digestant would seem to be kind of a —

THE WITNESS: It has some connection with the actual chemical nomenclature, but it is not truly the chemical nomenclature. If you look on page 808, chlorpheniramine, that is, I believe, the actual chemical name of that product. It has been chosen for the generical name. It is a cumbersome name to be used and that is why the major companies choose to promote it.

Q. Mr. Sperber, do you have an opinion as to whether a pharmacist who receives your catalogue which contains comparative advertising would be encouraged to illegally substitute in filling a prescription?

MS. DRISCOLL: Objection.

THE COURT: I will let him answer.

A. I have an opinion, and that is if the pharmacist is a law-abiding citizen and practicing his profession in the proper manner he would have no problem at all.

THE COURT: Let's put another question, though.

[Tr. 666] Let's assume that he's not so great. He has a little bit of larceny in his soul, and he sees this list.

Wouldn't that make it easier for him to do that?

THE WITNESS: Yes, it would make it easier for him, but by the same token it would deprive 99. some percent of the law-abiding pharmacists —

THE COURT: That really wasn't my question.

THE WITNESS: Okay, I felt that I had to get —

THE COURT: You don't have to get anything in. Mr. Cobrin will ask you any questions that he wants.

Q. Mr. Sperber, do you have an opinion as to whether a pharmacist would be more familiar with the name of a branded product or the generic name of the product?

MS. DRISCOLL: Objection.

THE COURT: Overruled.

A. Yes, obviously the pharmacists would be familiar with the name of the branded product until a product goes off patent which is 17 years, nobody ever trys to get across to him the generic name. There is no reason for it. When Ives details or promotes their product they promote cyclospasmol they never promote the name cyclandelate. It has only in the last couple of years that they had to use the name on the label.

[Tr. 667] THE COURT: Are mostof these drugs where there are generic lower priced generic equivalents, have they been patented, do you know?

THE WITNESS: Originally, yes, but now the patents have expired.

Q. Do you have an opinion as to whether generic drugs or the corresponding branded drugs are more expensive to the consumer? A. By far branded drugs are more expensive.

Q. Have you ever received, and I am referring to you now as Henry Scheine complaints about the appearance of your generic drugs, vis-a-vis, the appearance of the corresponding branded drugs? A. Yes, I have.

Q. Could you tell the Court about them? A. We purchase our generic products from a number of different contract manufacturers, and it is our intention to have the product as closely as possible duplicated in appearance of the national advertised brand. But sometimes the colors between different manufacturers get a little slightly off and every now and then when we purchase, for example — well, every now and then when we purchase a product from multiple manufacturers and the color does vary slightly a pharmacist does complain to us that he has [Tr. 668] problems in explaining to his patients why it was a slightly different shade of yellow this time that it was on a previous prescription.

* * *

BY MR. MARROW:

Q. What would result if your catalogue did not contain the names of the branded product and only contained names and prices of generic products? A. I think it would result in much confusion on the part of the customers because they wouldn't know what the products were comparable to and it would obviously result in lower sales by us.

Excerpts of Trial Proceedings

[Gringauz, Tr. 684] Q. Have you ever had a patient in your years of dispensing pharmaceutical products inquire as to who the manufacturer of prescription drugs are? A. Not a lay patient. They are not really concerned with who makes the drugs.

Q. Do you have an opinion based on your years of pharmaceutical experience as to what the function of color is to the patient as to the medicine he or she might take?

* * *

A. Based on my years of experience I have come to believe that the patient identifies the color and the same of the medication with a disease, such as a blue tablet for their high blood pressure, a white one for their heart.

And not only that they seem to associate this color of medication with the time of day.

THE COURT: What do you mean by that?

THE WITNESS: By that, they have the idea that they take their blue tablet at 9:00.

In other words, it not only is the association [Tr. 685] of the color and the size with a disease, but also there is a correlation with the time of day as to the frequency of administration of their medication.

Q. In your experience as a pharmacist have you seen patients comingle a daily regimen of pharmaceutical products they are supposed to take in a single vial? A. Oh, yes.

Q. Do you consider this to be a good practice? A. Absolutely not.

Q. Do you know how these patients determine which medication to take at particular times? A. In their mind they have their dosage regulated. It is a correlation between color and dosage.

For example as I said before the blue tablet they would take at 10:00 in the morning.

The red one they would take at three in the afternoon.

So quote often they have a vial in the hospital when they are admitted, and the nurse comes down tomorrow with a vial, and ten different colored capsules are in there, and they know that this particular capsule they take at a particular time.

THE COURT: Or think they know.

[Tr. 686] THE WITNESS: Yes, your Honor.

This is what they have been doing for years. I am talking first about the patient taking medication for chronic illness as opposed to Ambacute or Ampicillin or some kind of antibiotic. This is an association with the disease as well as with the time.

Q. Have you ever personally been involved in dispensing a generic non-look-alike to a patient who had previously taken a corresponding branded drug having a different appearance? A. Oh, yes.

MR. COBRIN: We have a number of pills, your Honor, if you like I would hand them to you as well as to the witness.

Excerpts of Trial Proceedings

* * *

Q. You have in front of you Premo Exhibit 13, which is Apresolin, 50 miligrams Ciba. A. Yes.

Q. What is the active ingredient there? A. Hydrochlorzine.

Q. So that it is clear, what would be the color? [Tr. 687] A. This is a blue tablet.

* * *

Q. I take it you have in front of you Premo Exhibit 14, which is hydralazene, 50 miligrams Lederle. A. Yes.

Q. What is the color of that? A. Pink.

Q. Have you ever personally dispensed Lederle hydralazene to patients, and I am talking about 50 miligrams to patients who had previously taken Ciba Gygees Apresoline? A. Yes.

Q. What had happened? A. The patient was very apprehensive. Sometimes the patient refused the medication and preferred the blue tablet.

Sometimes I was able to explain to them that it was the same by another company.

Q. What did you do in a situation where the patient insisted on taking the blue tablet? A. I explained to them that the only blue tablets I had were the 25 miligram.

[Tr. 688] And the patient was very happy if I would give them the 25 miligram [sic].

But the ironic thing is that the 25 miligram [sic] tablet which was blue, and I would like to point it out here, was also made by the same company, Lederle.

And in essence it just made him fell better. But it was the same company and it was just a different color.

Because Lederle for some reason makes a 25 miligram [sic] generic blue, and they make a 50 miligram [sic] generic pink.

THE COURT: So you gave him or her two blues?

THE WITNESS: Yes, but not what — in other words, they wanted the blue thinking that they would receive the Ciba.

THE COURT: I understand.

Q. Have you ever had problems — have you ever been involved in a situation where there was a generic non-look-alike for a patient who had previously taken a branded product of a different appearance where the patient was a Russian immigrant? A. Yes, quite often.

Q. What do you do in a situation like that? A. Not only Russian, we also have Spanish-[Tr. 689]speaking people.

And it is rather difficult, to say the least, because I cannot explain to them that this is the same drug that they perhaps received last month that was a different color.

And in all honesty, all I do is fill the prescriptions and put them in a bag and give them the medication, and hope when they go home that they will take it.

I don't know whether they understand it is the same drug that was a different color last month, or if they feel perhaps that the doctor changed the strength or the medication, but it is totally out of my hands.

I give them the medication and hope for the best.

MR. COBRIN: Mr Trost, would you hand the witness, please, Exhibit 15, which is Antivert, 25 miligrams [sic] Roerig.

Q. What is the active ingredient in that, if you know? A. Mequizine.

And what is the color? A. This is a yellow on one side and white on [Tr. 690] the other.

It is an oval shape.

MR. COBRIN: Would you hand the witness, please, Exhibit 18, which is Mequizine hydrochloride, 25 miligrams [sic] Lederle.

* * *

Q. Would you compare the color of 18 to 15? A. This is yellow through and through. It is not a two-color medication.

Q. This is 18? A. 18.

Q. Have you ever dispensed Lederle's Mequizine to patients who had taken Roerig Antivert, and I am talking about the 25 miligram [sic] dosate [sic] strength? A. Yes.

[Tr. 691] Q. And what is happening? A. Apprehension, I would say, and anxiety, some of the time.

Sometime they will take the medication and get home and just call me and ask me if it is the same medication.

I seem to have a less difficult time with this particular tablet because of the shape. It is a characteristic shape.

And half of it is the right color which allays some of the fears.

It is just if they turn it over, they don't see the white, and I think it's a 50-50 chance, for some reason it makes them a little more confident that it is the right drug, and most of it is similar to the drug that they have been taking, the shape and the color.

MR. COBRIN: Would you give the witness Exhibit 16, which is Antivert .5 miligrams [sic] Roerig.

[Tr. 692] Q. Have you dispensed that drug? A. Yes.

Q. What is the active ingredient in that? A. Also meclizine.

MR. COBRIN: Could you hand Exhibit 17, which is meclizine, Lederle, 12.5 to the witness? A. This is totally blue.

Q. When you say this — A. This is number 17.

Excerpts of Trial Proceedings

Q. What is the color of 16? A. 16 is a blue and a white layer. That is the trade color. The generic is all blue.

Q. Have you ever dispensed meclizine by Lederle 12.5 to people who have taken roarax 12.5? Yes.

Q. What happened? A. A similar situation. There is anxiety, apprehension. It is much easier to explain to the patient. They accepted it a little more frequently.

Q. Ives isordil sublingual 2.5 by Ives, what is the color of that? A. Yellow.

[Tr. 693] Q. 52B, Stuart sorbitrate sublingual 2.5 —

* * *

Q. What is the active ingredient in A as compared to B? A. Exactly the same.

Q. Have you dispensed Exhibit 52B — what I mean is, the drug of 52B to patients who had taken 52A? A. Yes.

Q. What happened? A. I think the patient — I am not really sure — I can't tell you. They have this blank look on their face when you explain to them it is the same drug by another company. It is just a different color. I have the feeling that they are rather apprehensive about the situation.

Q. 53A, you have 53A in front of you, which is isordil oral five milligrams.

What is the color of that? A. Pink.

Q. And 53B by Stuart sorbitrate oral five milligrams? A. Yes.

Q. Could you compare for the Court the active —

THE COURT: What is the color of that?

[Tr. 694] THE WITNESS: It is not only a different color, it is a different shape. It's green and it is oval in shape.

Q. Would you compare the active ingredients in 63A and B? A. The same, isozorbic dyanytric.

Q. Did you ever dispense Stuart's to a patient who has taken Ives? A. Yes.

Q. What happened? A. I get a blank stare some of the time and I have a feeling there again, I can't tell you what they're feeling inside. I try to go out and explain to them that it is the same drug by an equally good company and it is just a different shape and a different color.

Q. In connection with your telling patients that they're getting the same drug only with a different appearance, have you done this with people who are 65 and older? A. Yes.

Q. Do you have an opinion as to how these people who are 65 and older reacted to your representation as compared to people who are younger, say in their 40's, 30's? [Tr. 695] A. By in large the elderly patient is much more apprehensive about their medication, maybe because they're taking it longer, maybe because they have been around a little longer. When they're used to a particular color medication for many years it is very

difficult for them to accept the fact that it is a different color that it is the same drug.

Q. Have you ever been involved in a situation involving emergency treatment of a patient suspected of having an overdose wherein the appearance of the tablet is available and it was desired to learn what it was? A. It has happened several times.

Q. Could you tell the Court the most recent experience that you had? A. The most recent experience I had about two weeks ago. The emergency room doctor brought down to me a prescription vial which had been filled in the community pharmacy. The pharmacist had taken a shelf packet of a medication from the shelf and on the back it says acetominophen, which is tylenol.

In filling the prescription he wrote — he had the label and labeled it aspirin. So the child actually had an overdose on this which was lethal and the treament of both drugs are completely different.

[Tr. 696] The emergency room doctor brought the vial down to me. There were a few tablets left and he said, "What is it?" Is it really tylenol or aspirin?"

Well, I couldn't a hundred percent say what it was since the fact that tylenol by characteristics of the shape of it usually generic manufacturers make the tablet flat and level on the edges to resemble tylenol. Aspirin looks more rounded.

I told the doctor I could not conclude one hundred percent what it was. Based on the looks of the medication if I had to make an educated case, I would definitely go for the fact that the child had an overdose on the tylenol.

The doctor had really nothing else to go by on that, except at that point. So since the antidote for tylenol was relatively innocuous, you have to start it early, and hope that it was tylenol and later on the blood tests did confirm it was.

And I feel in this case and really any other case it has disadvantages for things to look alike that the emergency room doctors need something to go by.

* * *

[Tr. 698] Q. Is there a problem with look-alikes or non-look-alikes in antibiotics?

* * *

A. Actually if you received an antibiotic one day from a doctor and say it is amplicillin and next year the doctor gives you another prescription and it is a [Tr. 699] different color, the patient doesn't care if it is the same color as long as it works. It is not like with the elderly patient, the chronic patient, for their blood pressure, diabetes, the colors are important because they come to identify it as being right.

It may not be right or wrong, but in their mind this particular color is right and if it is right for them it somehow works.

Q. Mrs. Gringauz, do you have an opinion as to whether or not it is desirable to have generic drugs as look-alikes of corresponded branded drugs? A. Definitely. I wouldn't be here otherwise. I really feel —

Q. What is the basis of your opinion? A. It is primarily as a pharmacist. I am the last line person between that medication and that patient and we — you have to have confidence in the patient — they have to have confidence in you as well as in the medication at that time.

Now, I hand the patient a medication and they think I made a mistake. Even if I didn't make a mistake, sometimes psychologically they won't take it. If they do they swear it doesn't work. They have to feel it works. The patient becomes anxious and apprehensive if it is not [Tr. 700] something that they recognize is right.

I think the patient has to have some control over their destiny. Now, if they're used to a white tablet or a yellow tablet, if they don't get that yellow tablet, they have a right to question, am I getting the right drug, because I tell you sometimes they don't get the right drug. It is not automatically the patient's fault. I must confess that pharmacists make mistakes like anybody else. Not only that doctors make a mistake when sometimes they're in a hurry when they write a strength it might be in a different color, and the patient says, why am I getting white now since I had yellow.

I listen to them. You must listen to them. They're not all stupid. They know what they're talking about. They have a right to know. They have a right to question.

* * *

[Tr. 702] Q. Does competitive bidding enter into the purchasing at any stage? A. Yes.

Q. At what stage does it enter? A. Competitive bidding enters into the stage probably at two leves [sic]. I don't know if you're familiar with the Joint Purchasing contracts. It is a buying group — it is a buying group that sends out bids to competitive vendors for a generic drug. They'll get a bid and usually they'll award a contract to a vendor. This vendor gives a contract number. We are not bound by it. Usually they have good prices. They'll be awared [sic] the JPC contract for a particular item. It behooves me to buy from that vendor.

Now, some companies do not go along. They do not submit bids to Joint Purchasing in which case St. Johns independently goes to different vendors and asks them for contracts based on a

yearly volume of the three hospitals that are a part of the charities. We get our own contracts

* * *

[Tr. 703] through the companies directly.

Q. Have you ever rejected a drug product because of its appearance — a drug product provided by your Joint Purchaser? A. I never had to.

Q. Now, in your pharmacy, do you stock amitryptilene? A. I do.

Q. In how many colors? A. We don't use that many psychotrophic drugs. On that we probably have the orange by Roche.

Q. Do you have a generic also? A. By generic I don't know if you consider that generic. Roche is a big outfit. If you consider the generic, fine, I do. The original was a different company and in a different color. It is a generic even though it is a very, very, fine house.

Q. Do you also buy amitryptilene from another source other than Roche? A. First of all, we don't use many, so we don't.

Q. Do you recall having testified in this case at a deposition?

* * *

Excerpts of Trial Proceedings

[Tr. 704] THE WITNESS: I remember, yes.

Q. Did you not testify that you had also purchased amitryptilene from Merck? A. I said we had some Merck on the shelf.

Q. How did it get there? A. It may have been there from a long time ago because we do not use much of this particular product. I think it was there before the Joint Purchasing contract was awarded to Roche which must have been a couple of years ago.

Q. But the Merck product was a different color from the Roche product, correct? A. I am sure it is.

Q. Do you stock imipramine in your pharmacy? A. Yes.

Q. Have you purchased imipramine from more than one source? A. I have purchased imipramine from United States Vitamin. We do not use it. Many drugs of this particular nature, that is why I say there are some on the shelf but I do not purchase it because it was purchased before the awarding of the contract to United States Vitamin.

Q. Is the color of the imipramine sold by United States Vitamin different from the color of the tovernil on the shelf? [Tr. 705] A. I am sure.

Q. Either amitryptilene or imipramine an antibiotic? A. No.

Q. Have you ever received any inquiries in connection with either of those drugs about the color of the particular drug

dispensed, given the fact that this happens rarely? Have you ever received any inquiries? A. The imipramine that we'd use would be used in-house for the patients in-house, if at all. If the patient were on a similar drug on the outside and they came in for a different problem, may have come in for a medical problem. They happen to be on the psychotrophic drug secondary to another disease. The clinics that I fill prescriptions for are basically medical clinics. They're not psychiatric clinics.

I do not fill prescriptions for imipramine. I have not in an out-patient situation — I can't remember probably because I can't remember ever having filled prescriptions for my out-patient prescriptions.

Q. Can you ever remember a problem in an in-patient situation? A. Not specifically at this moment.

Q. Do you also carry in your pharmacy more than [Tr. 706] isozorbic dyanytric? A. Yes.

Q. And of ampicillin? A. Yes.

Q. Tetracycline? A. Yes.

Q. Doxicycline? A. Yes.

Q. And hydracyline? A. Yes.

Q. Now, what percentage of the prescriptions that you dispense are out-patient as opposed to in-patient in the hospital? A. I personally fill —

Q. The pharmacy. A. — or the pharmacy. We fill beteen [sic] ten to twelve thousand prescriptions per month. On the out-

patient we fill about — at least five hundred a week. That is a hundred a day, five days a week.

THE COURT: That would be about 2,000 a month?

* * *

[Tr. 707] Q. How many prescriptions do you personally fill per week? A. Between 150 and 200, I would say. About 30 a day minimum. Between 150 to 200 out-patients.

Q. You personally? A. Me personally.

Q. Have you ever had any inquiries about the color or change in color of isozorbic dyantric, ampicillin, tetracycline or doxicycline? A. Yes.

Q. And on what occasions? A. Which drug?

Q. Which drug have you had an inquiry? A. Ampicillin and isovdil.

Q. Can you please describe what transpired when [Tr. 708] the inquiry was made? A. Let's take the ampicillin. It is on an out-patient basis. Normally I don't have problems with an antibiotic on an out-patient.

One specific instance comes to mind. We have an emergency room which is open 24 hours a day. During the night when the pharmacy is closed we dispense to the emergency room the unit dose capsules which is by one vendor. The emergency room will give out to the patient three or four capsules and say to the patient, "You take these now, here is the prescription. You come back in the morning and get it filled."

The emergency room doctor gives the patient four ampicillin capsules in unit of use which is one vendor.

Q. Excuse me, unit of use? A. Unit of use.

Q. What is that? A. It is if an ampicillin capsule is individually wrapped it can be referred to as unit or unit dose. It may have the vendor's name on it, the expiration date. It is what we use for in-patients which is one vendor. The emergency room operator gave the four capsules to the patient and says, "Come back in the morning and get the prescription filled."

[Tr. 709] They come back in the morning and hand me the prescription and I fill the prescription for 28 ampicillin and the patient walks ten steps down and says, "You gave me the wrong thing."

Q. What did you say? A. I never disallow what the patient says. I went and looked at the prescription to see if it was ampicillin, and it was, so I didn't give the wrong thing.

Q. What did you say? A. I said, "What do you mean? Why did I gave you the wrong thing?"

The patient says, "Well, the doctor told me last night that you will give me the same thing what he gave me and this isn't the same."

I had to dig a little further into the situation to see that the ampicillin capsules that were given at night were given in the unit of use from a contract of one vendor.

I explained that to her and I think I got it across. You never really know. I think I did.

Q. Now, in connection with in-patients at the hospital, have you ever had occasion when a nurse has made an inquiry to you about the color of a product that you have dispensed for in-patient use? A. Yes.

* * *

[Tr. 710] Q. Now, if these patients were given a different color product because it was, in fact, a different drug, would they not in those situations also question whether you had given them the correct thing and could you explain to them in those instances? A. Yes.

Q. How would you explain to them in those instances? A. Well, as I said before, if it is a different [Tr. 711] color and if I don't call it to their attention first and they ask me, "Is this the right medication —" let's say that I give them a yellow tablet and they're used to a white tablet, I would try to check into it. I would see if there is a similar product or the same product in a different strength. Tetracycline which is an important medication for the chronically ill, it is not uncommon for a patient to say that I am used to getting it white, why the yellow.

When they say this to me, I double-check to see if there is a mistake made. I think this is a positive thing.

* * *

[Tr. 716] Q. How would you fill a prescription that said dispense as written? A. Today or then?

Q. Today. A. That happens to be a very nice question, because it happens on who has the money to pay for it.

If you have money to pay for the prescription and if the doctor writes on the prescription, dispense as written, you as a patient are very fortunate, you can get the same color every month.

If you are on Medicaid and the doctor writes dispense as written, unfortunately, this is not the case.

The patient gets the generic.

Q. I asked how you would dispense a product if it says dispense as written. A. It depends on whether you are going to pay for it out of your pocket or if the Medicaid is going to pay for it.

That is what I am trying to explain.

* * *

[Bloom, Tr. 733] Q. Doctor, what is the usual duration of use by a patient of Cyclospasmol, and could you explain your answer to the Court, please. A. The drug is often used in a long term chronic situation where the problem will be existent for a long time.

Q. Are you familiar with the expression "maintenance drug"? [Tr. 734] A. Yes.

Q. Is this considered to be a maintenance drug? A. In a broad sense that you are speaking of drugs that are used over a long period of time, yes.

Q. In your practice do you prescribe drugs for patients? A. Yes.

Q. Do you tell your patients anything about the appearance of the drugs when you prescribe them? And could you explain to the Court what happens? A. I frequently will describe the medication I am prescribing to the patient, telling them certainly about how often to take it, when to take the drug, what the drug specifically is for, and frequently what the drug looks like.

The latter part is important to many patients who are quite elderly or have difficulty in identifying specific medications.

Q. Do you have an opinion — strike that.

How long have you been a physician? A. My licensing in the State of New York has been 16 years.

Q. Do you have an opinion based on your years of experience as a practicing physician whether it is desirable from a medical standpoint for generic cyclandelate to be in [Tr. 734A] the same colors, size and shape of cyclospasmol? A. In a general sense I think that all drugs, specific drugs for a specific purpose should look exactly the same.

[Tr. 735] Q. Why is that? A. Well, it avoids the confusion that patients often have. They may, because of the dispensing, receive what is exactly the same medication, but it looks differently. This has happened and has often caused a great deal of confusion and anxiety on the part of the patient.

Q. I forgot to ask you this question, Doctor.

When you prescribe cyclospasmol, on the prescription blank, which line do you sign? A. For almost all drugs I sign substitution permissible.

Excerpts of Trial Proceedings

Q. Have you ever in the past received inquiries from your patients who were receiving generic medication which had an appearance different from the corresponding branded medication they had previously taken. A. I have received inquiries from patients who tell me that the medication they have just got is different from the medication they were previously taking or supposedly the same condition. And the answer is yes.

Q. Have you ever had a patient refuse to accept medication that was in a different appearance from that which he had previously taken? A. That she had previously taken, yes.

Q. She had previously taken? [Tr. 736] A. Yes.

Q. And which medication is that? A. The specific medication Isososorbide.

Q. Have you received, other than this lady, I take it, inquiries from patients who had received generic drugs that were not look alikes of corresponding branded drugs? A. Yes.

Q. Generally what is the nature of those inquiries? A. Well, the patient would call and tell you that he thinks the pharmacist made a mistake because the druge [sic] he got, the new prescription is different from the one he had previously taken.

Q. Based on your years of medical practice, do you have an opinion as to what function the appearance of a medication serves for a patient?

* * *

A. I feel that most patients use the shape, size, the color and other such things as identifying the specific use of the medicine. They may not know the name of the medicine but they know that this pill is for diabetes and that pill is for their heart, so they associate specific characteristics of each pill with a certain kind of condition that they have.

[Tr. 737] Q. Doctor, have you ever prescribed a medication to a patient that had already been on a number of other drugs? A. Yes, frequently.

* * *

Q. Can you explain to the Court what information you would give to such a patient, and if you like, I will hand you Premo Exhibit 51.

* * *

THE WITNESS: Frequently when there is an elderly patient with a large number of different medications, where there is quite likely to be confusion as to the drug to take, the time of the day to take it and such, I will instruct the patient about the new medication I am giving him, as to its nature. I might say this is a diabetic pill. It is a big white round tablet. You take it in the morning or evening with or without meals.

The kind of questions the patient asks you, should I take it with orange juice or water, et cetera.

[Tr. 738] At times it's not sufficient to get the patient on the proper regiment. And when I identify such a problem, I often make up a card, such as an example which has been presented.

Excerpts of Trial Proceedings

THE COURT: That's Premo Exhibit 51?

THE WITNESS: Yes.

* * *

THE WITNESS: Which has information as to how you take the pill, the name of the pill, both the trade name and the chemical name. When you take the pill, dosage of the pill. There are often two pills thay may look very similar and have different dosages. And I have also used a pill stapled to the card as a further identifying methodology.

Q. Do you explain the appearance of the pill to the patient? A. Yes. I tell them he is receiving a specific pill. I try to characterize it by its size, shape, color, any special unusual things. Some pills have flattened bottoms. There is a diabetic pill with such a description.

Q. Is Exhibit 51 a duplicate of a card made for a patient? A. Yes.

Q. What was the condition of that patient? A. This patient had a combination of a diabetic, [Tr. 739] hypertensive and arteriosclerotic heart disease.

Q. Do some of your patients, Doctor, take different medication on a daily basis and self-medicate? A. They always, almost always do.

Q. Do some of your patients who take different medication on a daily basis who self-medicate comingle their medication in a single vial? A. Yes, I would suspect that they do.

Q. Do you consider it to be a practice that you endorse? A. No, I do not endorse that they mingle the pills.

Q. How do these patients who mingle the pills decide what they take when?

MS. DRISCOLL: Objection.

THE COURT: No.

A. They have told me that they know it by the color, the form, the size of the pill.

THE COURT: I take it there is no generic for the last drug on Exhibit 51 which has a Ciba name on it.

THE WITNESS: There are other pills that do exactly the same thing and have the same composition.

Q. But you wanted this patient to have Ciba one? [Tr. 740] A. I wanted to give him the pill.

* * *

[Tr. 740] Q. Do you have an opinion as to whether or not a [Tr. 741] person who is considered to be more elderly might or might not suffer anxiety if they were taking a branded medication and were switched to the generic medication having the same active ingredient, only a different appearance? A. Well, in this specific instance I alluded to before, the patient was very disturbed about the change in what she thought was a different pill. And eventually I had to put her back onto a pill with a different mode of operation. Instead of under the tongue, she had to take it by mouth swallowing.

Q. Doctor, have you ever used the appearance of a drug for identification purposes? A. Yes.

Q. Could you just briefly explain that to the Court. A. At times patients will come to you who have already — these patients are already on other medication, given to them by another physician. And they often don't know the name, the specific name of the medication, but they can describe it. It is a small white pill used for my heart, or a big red pill used for something else.

And you may use this as a basis for attempting to identify the pill.

Also, it is a sort of a clue that the specific [Tr. 742] pill, you can show him the pill perhaps if you have it available or you can use the physician's desk reference, which has not all the pills, but a good number of pills in there reproduced. And you can show it to the patient and he may say, yes, this is the pill, and it has this kind of a mark on it.

THE COURT: Would you rely on that?

THE WITNESS: We have to at times. There are other situations where that's the only information we have. A patient may be brought into the emergency room in a coma state, as recently happened on the ward service, a patient took a good number of diabetic pills and came in a diabetic coma. And the only information we had is a big blue pill with a flat bottom, and this identified it as a specific diabetic compound.

THE COURT: What is that Physician's Desk reference with all the colors and all?

What is the purpose of that? Why do doctors have that?

THE WITNESS: The drug companies give it to you. It is established by a drug company that supports it and gives us all the medication, and has an identification section as to color and shape.

* * *

[Tr. 745] Q. I believe you also testified in other instances [Tr. 746] patients had made inquiries to you about a change in the appearance in the drug; is that correct? A. Yes.

Q. And in those instances were you able to explain to them satisfactorily so that they took the medication? A. I believe so.

Q. Do you have a close relationship with your patients? A. I should like to think so.

Q. That's important in the medical practice, is it not? A. It's important, yes.

Q. Now, is it possible, sir, that a patient who has seen you for one ailment may also be seeing another doctor? A. Yes.

Q. And in those instances could that other doctor be prescribing other medication to the patient? A. I would imagine so. I can't answer that question.

Q. And can you conceive of instances where the medication being prescribed by the other doctors identical in color and size to the medication you happen to be prescribing for the patient? A. I don't know. That might happen.

Excerpts of Trial Proceedings

[Tr. 747] Q. Is there any way you would know? A. If the patient came back to me and showed me some pills he was taking and I recognized them as not being mine, I might inquire where he got them and find out then that another physician gave it to him. But I wouldn't know unless he showed me the pill.

Q. Now, assuming that the patient was in a situation where another doctor had prescribed a pill that happened to look similar, would that patient be in trouble if they relied on the color, the color, for example on your pill chart? A. I would have to know what the medication is that they were taking. If there was side effects, it might.

Q. What hospital are you associated with? A. The Brookdale Hospital Medical Center in Brooklyn.

Q. And are you somewhat familiar with the medications stocked in the pharmacy at Brookdale? A. Yes.

Q. And does Brookdale carry generic product in its pharmacy? A. I believe so.

Q. Do you know whether Brookdale has carried the drug amitryptline from more than one source? [Tr. 748] A. I don't know that. I am not a member of the pharmacy.

Q. Have you ever prescribed amitryptline to a patient? A. Yes.

Q. Have you ever prescribed imipramine to a patient? A. Yes.

Q. Are you aware whether imipramine comes in different colors from different manufacturers? A. Yes, because of the basic problem we discussed. A patient told me he got a different pill. When I told him he would be receiving a certain type of pill, he came back and said, "My pill looks different from that and did you give me the right medication?"

Q. Did you assure him? A. I looked it up in the PDR as to whether or not there was a different company making the pill. I looked it up and found the specific pill and the same product and tried to reassure the patient that it was imipramine.

Q. And were you successful in reassuring the patient? A. Yes.

Q. Have you ever prescribed librium for a patient? A. Yes.

[Tr. 749] Q. Have you ever prescribed librium with substitution permissible? A. I would say almost to the point — not 100 per cent, but 95 per cent I write substitution permissible.

Q. Do you know whether there are drug products on the market which are the same chemical composition as librium, but which comes in different colors? A. I am unaware of it.

Q. And you don't know whether your patient got a black and green; is that it? A. That's a color of librium, black and green.

Q. You have never gotten an inquiry from a patient? A. No.

Excerpts of Trial Proceedings

Q. Now, do you know what kind of a drug hydrochlorothiazide is? A. Yes.

Q. What is it? A. It can typically be called a diuretic.

Q. Your deposition was taken in this case, was it not? A. Yes.

Q. Do you recall having testified that a patient who had been taking either a yellow tablet, diuretic, and [Tr. 750] was switched to a pink and he inquired about it? A. It was quite reversed. The patient was taking a pink form and inquired as to the yellow form I gave her.

Q. And were you able to reassure that patient of the change, the reason for the change? A. Yes.

Q. And do you consider it in your medical opinion a bad practice to have the same dosage form of that diuretic sold by some manufacturers in yellow and some in pink? A. I think it leads to confusion.

Q. Now, I would like to show you a Premo Catalog, Plaintiff's Exhibit 48, and show you at the top of the page, which is marked 520A, and asked if Premo in fact, according to that catalog, had sold the same diuretic in the same dosage form in those pink and yellow colors you just referred to.

(Handed to the witness.)

* * *

[Tr. 751] Q. Does it appear that it is sold in both yellow and pink? A. There is a listing on the page for hydrochlorothiazide

50 milligrams yellow, and in the next column says hydrocide tables 50 milligrams, peach.

* * *

[Tr. 752] Q. Did you ever prescribe drugs that are available in both the name brand and the generic but you prescribed them, "dispense as written"? A. Yes.

Q. And on what occasions would you? A. Diuretics particularly come to mind.

Q. You would say, "dispense as written"? A. No, I write, "substitution permitted."

Q. My question is, are there instances in which there exists on the market available both the initial name brand that was formerly patented and a range of generics?

Do you ever prescribe the name brand and sign, "dispense as written"? A. I have never done that.

Q. You don't do that.

Now, assuming you write a prescription for a patient, Doctor, how do you know that the pharmacy has, in fact, filled the prescription properly?

How would it be called to your attention if it did not? A. The patient might come to my office a month [Tr. 753] or two later and show me his pills. I might say, that doesn't look like it is a correct pill.

Or the patient might call me up and tell me what I gave him was not helping his condition.

I might ask him to come in again and show me what he is taking.

Q. It would have to be a communication from the patient to you? A. What I tell you now is hypothetical, because I can't remember an incidence of this occuring.

Q. Now, do you know whether the Physicians Desk Reference that the Court asked you about depicts all of the drugs accurately or are the appearances sometimes not quite right? A. The appearances are not always right — exactly right. I would say that most of the time they're almost good facsimiles.

About two years ago there was a problem with their color scheme and they sent us a new insert and told us to get rid of the old one. This happened about two years ago.

* * *

[Tr. 755]Q. Now, let's assume you had one of the blue-whites on your patient pill board, take this three times a day with a glass of whater [sic].

What if that patient were on both of those, could that patient reasonably rely on your pill board? A. In several different ways, probably. One, there would be a difference in the use of the specific drug. It would tell him it's under the tongue or by the mouth. It might be a different schedule of times. Maybe instead of once a day by this pill you might take this one four times a day.

If possible, I have the drug identification — either the company name or the logo or the number and the patient would likely see — if he looked that there is a different number or a different name —

Q. In other words, you would have to inspect these two blue and white pretty closely if he were on both of those drugs; is that correct? A. He would have to inspect them if someone gave him two pills that looked alike.

THE COURT: Would you give him a chart with two pills that look identical like that?

THE WITNESS: It is most unlikely. But I was asked if another physician would. We do ask our [Tr. 756] patients what medication they're on already. I see patients from another physician with a collection of pills. I am somewhat aware of the medication that the patient is already taking.

Q. Reliance on color could cause problems? A. As a single facet, yes.

Q. Have you ever known of a situation — an overdose situation involving vasodilators?

THE COURT: Can you get an overdose so that you will be in trouble?

THE WITNESS: I can't answer that, I don't know.

* * *

Q. What is the number that appears on the pills — what does that number indicate? A. The number on the pill is the

company's identification of the specific product. Not only the name of the product, but also the strength of the product.

* * *

[Stempel, Tr. 764] Q. Now, after World War II were there any advertising of drugs to the public? A. You're talking about prescription —

Q. Ethical drugs? A. Prescription drugs are not advertised to the public because it is not in the province of the consumer to purchase drugs without prescriptions.

Q. After World War II generally, were prescriptions [Tr. 765] written for drugs identified by brand name or a generic or chemical name?

I am talking about the period right after World War II. A. They were mostly by trademark designation or brand names or proprietory designation, which are synonomous.

Q. After World War II if a pharmacist — and I am talking about the period right after World War II, received a prescription for a brand name drug, did he have any discretion on how he filled the prescription? A. Would you repeat the question?

Q. After World War II when a pharmacist received a prescription calling for a brand name drug, did he have any discretion in the manner in which he filled the prescription? A. No, he had to fill it in accordance with the physician's direction.

Excerpts of Trial Proceedings

THE COURT: Were the generic drugs on the market at that point right after World War II?

THE WITNESS: To a limited extent.

Q. Prior to the substitution laws, were many prescriptions written for generic drugs? A. Very few.

Q. Why was this? [Tr. 766] A. There was no demand in the light of, as there is in the present, in the light of existing substitution laws or what is more — what is more usually called drug product selection laws.

Q. Has there been a trend one way or the other recently with respect to prescriptions calling for generic drugs as distinct from brand names? A. There has been a up trend. If I could cite statistics — by '66 there were approximately — I say approximately without giving the decimal places — approximately six percent of generics throughout the country.

Based on total prescription volume and it rose in 1978 to thirteen plus which I round off to approximately fourteen plus or minus and therefore it provides an impact of approximately twice over a twelve year span as far as increase in generics are concerned.

* * *

[Tr. 770] Q. Since 1949, when you became a licensed pharmacist, to your knowledge, has there been a practice — a general practice with respect to — generic drugs products and their appearances vis-a-vis, corresponding trademark products? A. Since I have been practicing pharmacy I have

found that the generic products usually have the same or similar appearnace [sic] as the branded products.

* * *

[Tr. 774] Q., Do you have an opinion, Dr. Stempel, as to whether or not Exhibit 4 shows the general practice of generic pharmaceutical manufacturers with respect to the appearance of the drugs they make, vis-a-vis trademark products? A. Yes.

I believe it does show the general appearance of generic products as compared to trademark products.

Q. Have you worked as a dispensing pharmacist since 1949 on occasion? A. Yes.

From 1949 until 1972.

Q. Based on your pharmaceutical experience, do you have an opinion as to what purpose the color is insofar as a patient is concerned, with respect to his medication?

* * *

A. As far as the purpose of the medication for the consumer, it indicates to the consumer the purpose, the therapeutic purpose for which he is to utilize, use said medication.

[Tr. 775] Q. Have you ever observed the patient checking his refill prescription medication that you have dispensed to him? A. Yes, I have.

Q. Based on your observation what was the patient doing? A. The patient was — wanted to be assured that he was obtaining the same medication on a refill that he had originally obtained.

Q. Have you ever had a patient request of you the name of the manufacturer of a drug product? A. Never.

Q. Are generic drugs detailed to your knowledge? A. Generic drugs are not detailed.

Q. How is the demand for generic drugs created if they are not detailed? A. The stimulus for the manufacture of generic drugs is based upon the drug product selection laws which have recently been instituted.

* * *

[Tr. 781] Q. Now, in connection with the drugs that you have provided, did you in any instance attempt to ascertain whether the particular drug in the same size dosage was also available on the market in colors different from what was on the chart? A. No, I did not.

Q. Do you know whether in fact some of the drugs shown on the chart do in fact come in different colors? A. They do.

Q. Do you know how many of them come in different colors? A. I don't know.

Q. Were you asked only to collect the look-alikes and not to collect the entire range of prescription drugs in each category? A. My request was to obtain look-alikes.

Q. Only? A. Yes.

Q. Do you know where the students you referred [Tr. 782] to obtained these look-alikes? A. These students obtained look-alikes from the pharmacies in which they were employed.

Q. Do you personally know whether any of the drug products on that chart are actually available in pharmacies today? A. I believe I have already answered that question, and the answer is I don't know.

MS. DRISCOLL: I ask your Honor that Exhibit 4 not be received in evidence.

THE COURT: No.

I'll receive it. If you want to tell me which ones are not right there and which ones have different colors, I will consider that too.

MS. DRISCOLL: We will be doing that on rebuttal.

THE COURT: Yes.

Q Now, I refer to the pharmacist's exam, Dr. Stempel, which has been marked as Defense Premo 3. A. That's correct.

Q. Now, turning to page 2, is hydralazine a generic or a trademark? A. In this case I believe it is a generic designation.

* * *

Excerpts of Trial Proceedings

[Tr. 784] THE COURT: Do you know of your own knowledge, leaving out what you heard from other folks proctoring, do you know from your own knowledge what 25 miligrams [sic] hydralazine comes in, what color?

THE WITNESS: I don't know.

I have never seen it.

Q. Do you know whether 25 miligram [sic] hydralazine in fact comes in more than one color? A. I don't know.

Q. When they put Ciba down in the little box there, that means that they have filled the prescription with hydralazine made by Ciba? A. If it is generic it requires the name of the manufacturer or the distributor of. If it is a trademark designation, according to law it only requires the trademark designation, which obviously everyone knows is the ownership of the specific company, if it has a specific strength.

THE COURT: So when they saw draw a circle around the color of the medication dispensed, you would have to know the color of Ciba's hydralazine, what it was?

THE WITNESS: Yes, your Honor, yes, sir.

* * *

[Tr. 793] THE COURT: Let's take this one on page 4.

THE WITNESS: Yes, all right, Nitro-Bid.

THE COURT: And let's assume that Eric Dahl, MC., signs substitution permissible.

THE WITNESS: Yes.

THE COURT: Now, he fills it with a generic.

And let's assume he puts on the label the [Tr. 794] name of the company.

THE WITNESS: And the generic name?

THE COURT: And the generic name.

THE WITNESS: Yes.

THE COURT: Does he also have to put on the label anything about the doctor having given him permission?

THE WITNESS: No.

THE COURT: Orally given him permission?

THE WITNESS: No.

But he should make that notation on the original prescription paper.

THE COURT: All right.

THE WITNESS: And he should also explain it to the patient.

THE COURT: All right.

Q. Now, do pharmacists from time to time advise people in the pharmacy, consumers, about over-the-counter medications that might be useful for given ailments they are asked about? A. Yes.

Q. Is there a certain relationship confidence that exists between pharmacists and the patient consumer? A. Assuming that the patient patronizes the [Tr. 795] same pharmacy continuously, the answer is yes.

Q. Now, is a pharmacist in the State of New York required to pass along to the consumer the saving after having dispensed a generic drug, as opposed to the more expensive name brand? A. In New York State the present law does not provide for the passing on of cost-savings.

Q. Now, do you have any knowledge of how a pharmacist would determine what price to charge a patient for a prescription drug? A. I am not an expert on prescription pricing.

But in essence there are two methods. There is the mark-up method and the professional fee method.

Q. And would you describe for the court each method?

First, the mark-up. A. I don't think I am in a position to explain mark-up. But I am in a position to explain professional fee because I am an advocate of the professional fee concept.

* * *

[Tr. 812] THE WITNESS: If this contains cyclandelate then the pharmacist should have on the prescription label the

word cyclandelate with the manufacturer [Tr. 813] or distributor's name thereon, without perusing it any further.

* * *

Q. You're saying they're not properly labeled; is that correct? A. I am saying that they're not labeled in accordance with the manner in which they should be labeled. Assuming there is cyclandelate generic in each?

Q. Yes, assuming that. A. I'd like to point out that this is labeled —

THE COURT: Which one is that?

Q. The number is on the bottom. A. 82TT. It is mislabeled. However, if one can state it is mislabeled — it is not as — mislabeled as badly as some of the others.

THE COURT: Why do you say that?

THE WITNESS: Because in this specific case [Tr. 814] the name of the manufacturer is listed but the point is it is mislabeled, your Honor. In this case — this stands together.

82BB are not too bad as compared to this, on a comparative evaluation basis. Here again, I would say these five are mislabeled and this is also mislabled but it is not mislabeled as badly as the other five.

* * *

Excerpts of Trial Proceedings

[Tr. 815] Q. In questioning by Miss Driscoll, there was a statement made about trade names or brand names belong to particular companies.

When a pharmacists sees or hears the name of a [Tr 816] drug product, does the pharmacist usually know whether the name is a generic name or a brand name? A. He usually knows.

Q. Now, if it is a trade name, does the pharmacist usually know which company owns the trade name? A. Not necessarily. He may have to consult a suitable text, the American Drug Index.

Q. And your experience, do patients when they see or hear the name of a drug usually know whether it is a generic name or a trade name? A. They don't know anything. They don't usually know anything concerning medication.

* * *

THE COURT: You say the pharmacist usually will know whether a drug is — the name that is on the prescription is a brand name or a generic name?

When you say usually, I take it sometimes he doesn't?

THE WITNESS: Yes.

THE COURT: Is it a problem educating people [Tr. 817] about what the generic name is?

THE WITNESS: There are so many advances that it is difficult to keep up with the times. If he sees a specific name and

he's not aware of it, he can consult the American Drug Index which will indicate to him whether it is a trademark designation or not.

THE COURT: Take some of those bottles and assume for the moment, which we don't know one way or the other, assume for the moment that the druggist is within perfectly good faith, and assume for the moment that it said — the prescription said, "substitution permitted."

Could that be — and they put in cyclandelate — is that possible that they — that they thought that the Cyclospasmol was the generic name?

THE WITNESS: I believe, your Honor, they did this in good faith. I believe the law is still in its infancy as far as its span of time that it has been invoking and we really can't condemn the pharmacist. He gave the patient the generic. It just that he may not be fully aware —

THE COURT: What is the reason for him to mislabel it unless he's trying to — unless he does [Tr. 818] it deliberately? What is the reason for him to mislabel it and put in cyclandelate, in your experience?

THE WITNESS: I believe it takes time to be familiar with all the intricacies of the law and he may not be knowledgable concerning the intricacies of the law.

* * *

[Tr. 819] THE COURT: That was the one where it was for Cyclospasmol and they came and they gave them cyclandelate.

They were allowed because it said, "substitution permissible" but they put on the label Cyclospasmol.

Here is one that says generic Cyclospasmol which would seem to indicate, perhaps wrong — perhaps I am wrong, but would seem to indicate that they think — I won't speculate.

THE WITNESS: May I say something?

I believe this is with good intent. I can cite specific examples as I have in my deposition where novobiocin sodium was prescribed to a patient and an unscrupulous pharmacist gave a cold capsule —

* * *

THE COURT: What could they have been supposing if they were in good faith?

[Tr. 820] THE WITNESS: They were supposing that they were providing the patient with the correct medication and they may not have been knowledgable concerning the intricacies of the labeling.

* * *

[Calodny, Tr. 822] Q. Is there a hospital policy or guideline which you follow when purchasing drugs for the hospital? A. Yes.

We have a hospital therapeutic committee [Tr. 823] for the hospital and a board of directors.

And they informed me to purchase at the best possible price and to save money for the institution.

Q. Are you a member of the pharmacy committee? A. Yes.

I am the Secretary of the Pharmacy Committee, and I also conduct the meetings of the pharmacy committee.

Q. Do you purchase generic drugs in accordance with the guidelines set forty by the committee? A. Yes.

Q. Do you follow any particular practice when you purchase generic drugs? A. Yes, I do.

I try to purchase generic drugs from companies that have representatives where at least I can determine the quality of the product and how it is manufactured.

At least I could have somebody to relate to. And I also visit pharmaceutical companies on occasion to visit their manufacturing processes.

Q. When you purchase these generic drugs, do you look for them in any particular characteristic? A. Yes.

I try to purchase the generic medication, [Tr. 824] so that it looks in the same size, shape and color as the original brand.

Q. And would you give the court a few examples of some of the generics that you purchase? A. We have the Chlorpheniramine.

Excerpts of Trial Proceedings

THE COURT: Before you go on listing those, what kind of hospital is yours?

Is it a general hospital?

THE WITNESS: Yes, it is, your Honor.

It is a general hospital, a proprietary hospital. We have mainly a geriatrics population of the hospital.

THE COURT: Thank you.

You were going to give us other examples.

THE WITNESS: Yes.

I also purchase Rauwolfia Serpentina that resembles Robaxin.

I also purchase Basocodyl that resembles Dulcolax.

Q. And I take it you purchase some others too? A. Yes, quite a few.

* * *

[Tr. 825] Q. The ones you listed, are they the same size, shape and color as the brand name? A. Yes.

Q. And in your experience what is the benefit to you and the hospital to purchase generic drugs in the same size, shape and color as the brand name? A. It makes it easier for the purpose of identification.

I dispense a particular medication to the nurse, and she has to administer the medication to the patient.

Now, if it resembles the original brand name, there is no question about it, she is pretty certain that, well, this resembles the original brand, and there is no question in her mind that this is the proper drug.

And also the patient, who may have been on this medication before? The hospital recognizes this medication and says, yes, this looks like the proper medication for me, and the patient complies and takes the medication.

Q. Have you ever had the occasion to purchase and dispense a drug that was a different size, shape and color than the one previously purchased and [Tr. 826] dispensed and caused the problems which you just related? A. Yes, I did.

There was a time when we had in stock a brand of Beachum Totacillin.

This was a brown and orange capsule.

Then I purchased Smith, Klein & French brand of Ampicillin, which was a different color and this created problems.

Q. What were the problems that arose from dispensing the SKF brand? A. The SKF brand, and I have a sample here with me.

This was part of the problem, resembled the Macrodantin of Eaton Laboratories.

I then got calls from the nurses and some doctors, hey, is this the right medication, what are you sending us. They wanted you to confirm it.

As a matter of fact, a couple of nurses even called me at my home to question this particular medication, was this the right one.

So we did— I never purchased that brand again and I went back to the purchase of the Beachum brand of Totacillin, Ampicillin.

Q. Were there also patient problems that [Tr. 827] resulted from the switch to the SKF? A. Yes.

Some of the patients refused to take the medication, thinking that it was the wrong thing.

Now we have, as I mentioned before, primarily a geriatric population at the hospital.

And a lot of these people are very finicky.

And if you give them something that doesn't look like they are accustomed to taking, they will refuse to take this medication.

* * *

How do you know that the patients refused to take this medication? A. Since we have a small hospital some of the nurses would notify me verbally, and also on the patient

medication chart they will indicate on the medication sheet, refused, patient refused medication.

Q. And you noticed this with regard to the SKF brand? A. Yes. We did see cases of this.

[Tr. 828] Q. Did you report this incident regarding the confusion? A. Yes.

I spoke with my sales representative from the SKF Company, and informed him that your product looks identical to the Macrodantin of Eaton.

And I said, this created quite a confusion at the hospital, and would you please get back to your sales people and to your production people and notify them that this is causing these problems.

Q. Macrodantin is different from Ampicillin? A. Yes.

It is a different chemical and used for a different purpose.

Q. Before writing prescriptions are there occasions where a doctor would consult the pharmacist regarding the availability of a particular drug? A. Yes.

On occasions I had physicians calling me and requested a particular brand because they had an old patient, and this man or woman is accustomed to taking a particular medication that looks in a particular way.

And if this varies in some way they say that this patient would not take the medication.

Excerpts of Trial Proceedings

[Tr. 829] An example of this was the Parke Davis brand of Dilantin which has an orange brand around it. And the doctor requested me to take this particular brand because he knew if we attempted to use some generic brand that didn't look like it the patient would refuse to take it.

Q. Is Dilantin a short term for long-term drug? A. A long-term drug usually used in epileptic cases to prevent seizures.

And if the patient doesn't take this medication serious effects could result.

Q. As an experienced pharmacist, do you have an opinion as to the use of look-alike drugs used for long-term? A. I definitely feel that a medication that is of the same size, shape and color as the original would certainly be accepted and taken by the patient.

This aids in patient compliance in my opinion. And therefore the benefits of the medication are therefore given to the patient.

Q. Are you familiar with Forrest Laboratories? A. Yes.

[Tr. 830] They are a generic drug manufacturer.

Q. And you purchase generics from Forrest? A. Yes, I have.

Q. Would you just name one or two? A. I have purchased a nitro glycerine capsule and a hydrochlorithiacide tablet.

Q. Is that the same size, shape and color as the brand name? A. Yes.

They are the same brand name.

Q. Are you aware of a drug that was sold by Forrest with the name Cyclanfor? A. Yes.

That is a generic cyclandelate.

Q. Do you know what color Cyclanfor was? A. That was a green color.

Q. Are you familiar with Cyclospasmol? A. Yes.

Q. And what color is that? A. That is the —

Q. The 200 or 400 miligram [sic]. A. The 200 miligram [sic] is blue, a blue capsule, and the 400 miligram [sic] is a blue and red capsule.

Q. Now, how did you become familiar with the [Tr. 831] Forrest Cyclanfor product? A. In October of '77 I attended the New York State Council of Hospital Pharmacists Convention.

At that time it was held at Tanament in the Poconos, and Forrest Laboratories had a booth at the convention.

And I spoke with one of the salesmen and he informed me they had a cyclandelate which was in a green color.

Q. Did you purchase that cyclandelate in the green color? A. No, I didn't, because this incident with the SKF

penicillin was still fresh in my mind, and I said, I prefer not to purchase this in a green color.

I would like it in a blue color.

Q. To your knowledge is Cyclospasmol a long-term drug? A. Yes. This is usually used as a long-term drug, yes.

Q. Are the hospital purchasing records for Parsons Hospital categorized by drugs? A. No. They are categorized only by company.

* * *

[Tr. 832] Q. Are you familiar with the brand name for Amitripolene? A. Yes.

Q. What is that? A. Elavil.

Q. Do you know what color Elavil is sold? A. Elavil is in six different strengths. Each strength has a different color and each tablet has a little different shape.

Some are larger and some are smaller.

Q. Is there a different color for each dosage strength? A. Yes. There is definitely a different color for each dosage strength.

Q. Do you know who makes Elavil? A. It is made by the Merck, Sharp & Dohme Company.

[Tr. 833] Q. Do you know how Merck, Sharp & Dohme promotes its various colors in industry publications? A. Yes.

They show the pictures of the different tablets, and they show that each one, each strength has a different and distinctive color.

Q. Does that color serve to identify each tablet? A. Yes, definitely.

* * *

[Tr. 835] Q. Do you ever use the Physician's Desk Reference? A. Yes, I do.

Q. What do you use it for? A. Well, I am often in my work — I act as a consultant to nurses and physicians. So am often asked questions about particular medications, as to what their usages are, what their adverse reactions are, or sometimes a patient might develop an allergic reaction and the doctor would wish to know, did this particular drug cause this particular reaction or is it possible that it occurred.

THE COURT: Do you ever use the photographs?

THE WITNESS: In the physician's desk reference?

THE COURT: Yes.

THE WITNESS: Yes.

THE COURT: What do you use them for?

THE WITNESS: I use them, as I would, as I had mentioned before, if I wish to use a generic I want to make sure that the generic looks like the original.

THE COURT: All right.

Q. I refer you to what has already been marked as Plaintiff's Exhibit 32, which is the 1979 edition of [Tr. 836] desk reference, and ask if on page 421 there is a Parke Davis product with an orange band?

Is that the product which you testified about on direct? A. Yes, this one here.

Q. And I draw your attention to the footnote on that page, and ask if it makes any reference to the banded product which you just referred to. A. It says the color combination of banded capsules is a Parke Davis trademark.

Q. Had you ever stocked in your pharmacy a generic product which was not a look-alike? A. Yes.

Q. Now, I believe you testified that you have purchased from Forrest Laboratories two generic products, hydrochlorothiazide and nitroglycerine. A. Yes.

Q. Do both of those products in the form you purchased them from Forrest have the same appearance as the name brand product? A. Yes, they do.

* * *

[Olson, Tr. 838] Q. Are you employed? A. Yes, I am.

Q. By whom? A. By IMS America Limited.

Q. How long have you been employed by IMS? A. I joined them in August a year ago, 1978.

Q. And can you briefly describe what business IMS is in? A. IMS is a world-wide organization whose prime purpose is to collect and disseminate information relative to prescribing patterns of physicians, treatment patterns of physicians, as well as drug, hospital, federal government purchase of pharmaceutical type and health care type products.

* * *

[Tr. 843] Q. Now, can you determine based upon the information from your Audatrex sample and any report of prescriptions in that sampling for Cyclospasmol, approximately how many physicians in the United States do prescribe Cyclospasmol? [Tr. 844] A. Yes, we can.

Q. What is your estimate? A. In the range of about 15,000.

Q. Did you give that information, you being IMS, to Dr. Lipstein? A. Yes, we did.

Q. Now, I will show you what I have marked as Plaintiff's Exhibit 127 through 129 and simply ask you to identify briefly what these are?

(Documents shown to the witness.)

A. Plaintiff's Exhibit 127 is a therapeutic category report which is one of the reports of the National Prescription Audit. It is the issue date December '76.

Information displayed in here are prescriptions as written by physicians for the years 1974, '75, and '76, and for the months July through December of '76.

Q. Does that specifically show the number of prescriptions written for Cyclospasmol? A. Yes, it does.

Q. Would you turn to the next exhibit?

THE COURT: How many for Cyclospasmol does it show?

THE WITNESS: In the year 1976 for the full year there was approximately 159,000 new prescriptions, 1,352,000 refill prescriptions —

* * *

Total prescriptions, 1,911,000.

Q. Could you identify the next two exhibits also, as briefly as possible? A. Plaintiff's Exhibit 128 is a therapeutic report National Prescription Audit for the period ending December of '78.

Q. Does that show similar information about Cyclospasmol? A. Yes, it does.

Q. And Exhibit 129? A. Exhibit 129 is from the National Prescription Audit Therapeutic Category Report for the period ending October 1979.

Q. And that shows Cyclospasmol also? A. '79, yes, that also shows Cyclospasmol.

Q. Now, do you have a practice or policy at IMS as to whether or not the names of any patients or physicians that

might have participated in your data gathering activities remain confidential? A. They must remain totally confidential.

* * *

[Shinbach, Tr. 859] Q. In your professional career as a psychiatrist, could you estimate what percentage of your patients were over 60 years of age? A. Approximately 70 per cent.

Q. During the past two years can you estimate what percentage of your patients have been suffering from cerebral arteriosclerosis? A. Of the 70 per cent I would say two-thirds have had cerebral arteriosclerosis, or indications of that condition.

Q. Can you tell the Court what some of the symptoms a person would exhibit if he was suffering cerebral arterisclerosis [sic]? A. The typical symptoms of that condition are confusion, disorientation, memory impairment, cognitive impairment, by which I mean certain kinds of disorders with the thought process, including impaired judgment, poverty of information, that kind of thing. And in addition impairment of affect, by which we mean the regulation of mood is also characteristic of that condition.

Q. Is Cyclospasmol a drug which is sometimes prescribed for persons suffering from cerebral arteriosclerosis? A. Yes.

Q. Would you describe what effect Cyclospasmol [Tr. 860] would have on such a person? A. Well, in theory and in the hopes of a physician, it's intend [sic] to dilate the cerebral arteries, increase the blood supply to the brain and improve a marginal situation of imparied [sic] oxygen supplied to the brain.

Q. Have you ever prescribed Cyclospasmol to any of your patients? A. I have on a few occasions.

Q. What general age group were the persons for whom you prescribed Cyclospasmol? A. These are people in their 70 to 90 year range.

Q. Were these persons frequently taking more than one medication? A. Quite frequently.

Q. Could you describe what other types of medications such patients might be taking? A. Yes.

Very often a person who has artery impairment in the cerebral arteries would have arterial impairment in coronary arteries, vessels to the kidney and other organs. So such a patient might be taking one or more cardiac medication, such as a digitalis preparation and possible Inderal. They might be taking a diuretic or electrolites or a coronary artery dilator. That would be a typical situation.

[Tr. 861] Q. How many of these drugs might a typical patient with cerebral arteriosclerosis be taking at the same time or say during the same day? A. Well, it's not uncommon that a person might take all of them. But very frequently a person might take two or three from that group.

Q. Are some of these or many of these patients self-medicating? A. Certainly some of them are.

Q. And are some of the patients who are self-medicating exhibiting the symptoms of cerebral arteriosclerosis as you described previously? A. To a greater or a lesser degree, yes.

Excerpts of Trial Proceedings

[Tr. 862] Q. And in your opinion is it safe for such persons to be self-medicating? A. It may not be entirely safe; in some cases where the forgetfulness, let's say it's minimal, it may be safe enough.

Even when it is entirely safe there may be no alternative when you are dealing with a person who is widowed, isolated and unable to afford nursing care and so forth.

Q. Are there potential danger if one or more of this — of these multiple drugs are taken on an incorrect schedule? A. Yes, there are many great dangers.

Q. Can you describe what they might be, under what circumstances? A. Well, for example, if the patient were taking Cyclospasmol three times a day, and instead, because of confusion, took digitalis three times a day, there could be any range of complications from mild disorientation to death.

It could be very serious.

* * *

[Tr. 863] Q. To your knowledge have patients who are taking multiple medications during any given day ever fallen into this problem of confusing one medication for another? A. Oh, yes, definitely.

* * *

Q. Have you ever treated a patient who was taking more than one medication, and was in the habit of carrying various pills or the forms of medications in a single unmarked container? A. Yes.

[Tr. 864] That's rather common.

Q. Is this a practice that you encourage? A. No.

Q. Well, what do you do when you come across a patient who is doing such a thing? A. Well, if they are getting along all right with that system and it is working for them, I don't interfere, although I would not recommend it.

If they are confusing the medication in some way or seem to be in danger of making a confusion like that, then I attempt to get them to keep the medication separate by type.

Q. Has it ever occurred that you made such an attempt but the patient has continued with his previous practice? A. Oh, yes.

I have in mind one such patient who is very proud of her enameled and very beautiful pill box and likes to carry them that way.

Q. In communicating with a patient during a consultation during the subject of prescription drugs that the patient may be taking, do you or the patient ever use the appearance of the drug to describe it? A. That's not infrequent.

[Tr. 865] Q. Can you describe how that might come about? A. Very often the patient will not be familiar with the generic or the brand name of the patient and he will tell me, I am taking these white heart medicines from my internist, Doctor so and so.

And you are the doctor who gave me my yellow medicines for my mood.

And another doctor gave me this or that for gout.

Q. Does the appearance of the drug ever become used in instructing the patient on the use of it? A. Yes.

Psychiatrists have found that it is best to talk to patients in their own language.

So when a patient speaks to me in pill colors, I respond in the same idiom.

* * *

[Tr. 867] Q. Does the color of the drug ever come up in these particular consultations? A. Yes.

In what way? A. Well, for instance, even a patient who is given a vial with a label on it, a brand-name on the label would say that is the yellow pill I take three times a day.

Q. In your experience, have you observed the patients use the color of their pills to stay on schedule? A. They do.

Q. Have you ever had a patient who was taking two or more pills that had the same general appearance in color, but were different medications? A. Yes.

Q. Has this ever caused confusion in the patient? A. It led to considerable confusion in a number of instances, and one I remember recently, and that is the one I referred to in the deposition.

Q. Could you describe that one? A. This was a patient with, an elderly woman with an agitated depression. She lived alone. She was widowed.

[Tr. 868] She had a concerned social worker who saw her once a month, for her agitated depression.

I prescribed Mellarill, 10 miligrams [sic]. That is the brand name.

She was to take a total daily dose of six a day of those.

She mixed it up because the Mellarill is a green-yellow, even to me with fairly good eyesight looks similar to the yellow Elavil.

There is a difference if you look closely in the right light.

And the size is about the same.

So she was taking three a day, six a day of the antidepressant and three a day of the other instead of the six I prescribed.

As a result she became confused. Her blood pressure dropped and she was falling. The depression far from feeling became worse. Her agitation became worse. Her vision was more blurred. She was less able to distinguish the medicines.

It was a vicious cycle of effects that compounded one another. And the social worker called me in a complete panic when she found the woman bruised from falling, et cetera.

[Tr. 869] THE COURT: What did you do?

Excerpts of Trial Proceedings

THE WITNESS: The social worker also not being accustomed to drugs, was confused as to which drug was which drug.

We figured it out. Amazingly she had gotten the drugs into the wrong vials. We did work it out.

The social worker Scotch-taped the proper pill to the proper vial. I thought this was ingenious. And in time the woman did get it straight. It did not happen automatically though.

Q. Are some of the patients you are treating taking maintenance drugs? A. Many.

Q. And what is a maintenance drug? A. A maintenance drug is a drug which a patient takes on a prolonged basis, and the feeling is without continued ingestion of that drug, maintenance on that chemical, the person's condition would recur.

* * *

[Tr. 870] Q. What effect does the color have on the patient? A. Well, I think the sameness of color helps to keep from disrupting the patient's habits.

They feel that they are doing the right thing. It is an established regimen with them.

They go through the paces day after day taking these necessary medications without a second thought, which is by far best with many of these patients.

Excerpts of Trial Proceedings

Q. What do you think would happen if a patient received a refill of the prescription in a different color or in a different appearance? A. It would call for adjustment and establishment of new patterns which could be difficult with a patient with some confusional state.

Q. Have you run across such patients that have received pills they were previously taking in one form, and somehow or another the same drug has been offered to them in a different capsule or tablet. A. Yes. That does happen.

Q. And what does the patient think about?

* * *

[Tr. 871] Q. What did they tell you they thought about? A. I hear about it because they come to me and complain. They call and complain. They suspect that the pharmacist has given them a wrong drug, filled a prescription incorrectly.

They suspect that I have written the wrong dosage. They think something is wrong and they want to know what is going on.

As a matter of fact, as the physician I also when I first hear it, my first hunch is that something is going on, and later on it turns out that it was correctly filled but with a different product.

Q. You say this has happened to you in your actual practice? A. Yes.

Q. Can you relate any examples? A. It happens with my in-patient practice, not infrequently, because that is because the

pharmacist of the hospital is totally in charge of what is dispensed.

The hospital by-laws allow a physician to prescribe by brand name, but it will be filled generically in this day of cost consciousness in hospitals.

[Tr. 872] So I never know what the patient will get if I prescribe a certain drug.

At least I don't know, but I do know the chemical. That I am sure of.

So if the patient comes into the hospital and gets a medication they have been buying by brand name, and the hospital fills it with another product of the same type, I will get questions about that.

And they say, you said you will continue me, you are changing my medication, why, this has worked so well, the nurses are making a mistake, that kind of thing.

And if it is an out-patient they call and I have to check with the pharmacist and the secretary has to confirm whether it is the same substance.

Q. Have you ever had a case that the patient ever thought that the other drug was not working the same as the original drug, although it is the same chemical and different appearances? A. I have had a number of cases where the patient has said these were more affluent patients than normal, but they say, look, Doc, if you are giving me something just because they are cheaper and it is not as good, I don't want you

to spare money, this is [Tr. 873] important, this is important to me or she is my wife, whatever the situation may be.

Q. And does any particular drug come to mind where this has happened?

I was asking you for a specific instance if you can remember one, if not just tell us that. A. This happens in a lot of different situations. It happens to psychiatrists a great deal, at least it did with Lithium.

Q. What is Lithium? A. A salt related to common table salt. It comes out of the ground and not made in the laboratory. It is used for manic depressant illness.

No patent was able to be used by — for Lithium to my knowledge, because it wasn't made by any company. And it was in existence for thirty years and used here and in Europe for different reasons.

So three big companies jumped into the market, at least three I would say, with their own size and shape and form of Lithium.

One was a capsule. One is a tablet, a large tablet of a different color, and there is another one which I think is a capsule of a different color still.

So I write Lithium and the druggist fills [Tr. 874] it according to his preference.

And if a patient has been in one pharmacy or the druggist or supplier changes, I get a call as to what is going wrong.

Q. After you get that call what would the nature of the conversation be, or what has the nature of the conversations been between you and a patient who questions the drug for that reason. A. Again, am I getting the correct thing, is it the right side [sic], will it hurt me to take it.

Q. What do you tell the patient? A. Once I have confirmed that it is the correct chemical, I tell them it is really the same although it is a tablet and a capsule, and although it is a different color and so forth.

Q. After that explanation is given, are there generally future problems with respect to refilling the prescription and the patient's reaction to it? A. Probably not, unless they then get the third preparation of Lithium and have the same question again.

Q. Have you ever worked in an emergency room of the hospital? A. Yes, I have.

[Tr. 875] Q. Could you describe under what circumstances? A. I rotated through the emergency room at the Montefiore as an intern, and Gracie Square maintains a small emergency room where I have been called on occasions over the past ten or twelve years.

Q. Have you been present ever when a patient suffering from an apparent drug overdose was brought into the emergency room? A. Yes.

Q. Could you describe the procedure of such a case? A. Well, it depends on the patient's condition.

We see a number of suicidal patients. A patient might walk in saying they are — have taken an overdose or might be carried in unconscious.

If they are unconscious and their respiration is failing and you are concerned about their life you go right to work on that, and then ask questions later.

If they are alert and tell you they have taken an overdose, then you get as much information then as you can before instituting treatment.

Q. Is it important at one point or another during this emergency procedure to identify the drug or [Tr. 876] drugs the patient has taken? A. It is highly desirable, yes.

Q. Why is that? A. Certain drugs have specific adverse effects when taken in excessive amounts.

For instances, the barbiturates are infamous for depressing respiration.

So if a person comes in and has OD'd on phenobarbitol, you know that you want to have a resuscitator there, you want to have oxygen there. You might want to call the cardiac team which is especially well-equipped for that type of situation.

You might want to call an anesthesiologist. If a person has been sniffing — that is not an overdose, but if a person has taken too much digitalis, it would have primarily cardiac effects and you might want to alert the dialysis unit, that sort of thing.

Q. In the process of identifying the drug or drugs which that emergency patient has taken, is color of the drug ever used,

and if so, how? A. Well, you use every possible clue. And color could be very important. It might be the only thing.

A family member or a policeman or an ambulance driver might say, I don't recall know, Doctor, [Tr. 877] but I saw these white pills lying all over the floor, or these yellow capsules.

Of course, if you can make a more definite identification of the substance, if you are lucky enough to see the actual capsule and you can track down the identification number, if you know the patient from your own clinic or you know the doctor and you know what has been prescribed for that patient, that is the best.

But in a great many instances, we are in essentially an articulate situation where nothing but sight identification might be there to help you.

Q. Are there any charts or aids commonly kept in emergency rooms for which such a sight identification might be helpful? A. Yes, there are.

In the PDR courses, manual, it is the primary source.

Q. How does the PDR help? A. It has a product identification section with many or most available products pictured there.

Q. In your experience as a doctor, have you ever known a patient who associated the color of a drug with its manufacturer? [Tr. 878] A. That is not common. Most people really don't care about the manufacturer.

Excerpts of Trial Proceedings

Q. With what do they associate the color of the drug? A. With the effect of the drug.

That color pill is for my heart. That is for my gout. That sort of thing. That is for my diabetes. They associate it with the doctor who gave it to him.

Sometimes they associate it with a therapeutic effect or a pleasant side effect.

* * *

[Tr. 880] Q. And what was the dosage for Elavil? A. Twenty-five milligrams.

Q. Did you know at the time that you prescribed them that they were both yellow tablets? A. If I had thought about it I would have known, but it didn't occur to me until the problems arose.

Q. Could there be situations in which patients see you for one problem and then see another doctor for another problem? A. Very often.

Q. Is it possible that those patients who see another doctor subsequently would receive medication about which you would have no knowledge? A. Yes, it is.

Q. Now, in addition to this case of the Mellaril and the Elavil, both of which are yellow, are you aware of any other drug products on the market which are different medications but which are the same colors? A. Yes.

Excerpts of Trial Proceedings

Q. Are you also aware of the existence in the market of the same medication in the same dosage form, but in different colors? [Tr. 881] A. In some case I am aware of that.

Q. Have you ever prescribed Librium? A. Certainly.

Q. And when you prescribe it, do you prescribe, "dispense as written"? A. No.

Q. I show you what I have marked as Plaintiff's Exhibit 135, and ask if one of the products on that sheet appears to you to be Librium?

(Exhibit shown to the witness.)

A. Yes.

Q. Which one? A. The one beside the Hoffman-LaRoche.

Q. How did you recognize the Librium? A. It is black and green and I see the third one is also black and green, but I don't recall Librium having a CF on it, if that is the mark.

Q. Do you recognize any of the other capsules on 135? A. No, I don't.

Q. In your experience, have any of your patients for whom you prescribed Librium received a color other than green and black for that dosage form? A. I don't recall it being mentioned to me.

[Tr. 882] Q. Now, have you ever prescribed any barbiturates in your practice? A. Very rarely.

Excerpts of Trial Proceedings

Q. Have you prescribed barbiturates that come in different colors? A. Yes, I have.

Q. Have you ever had any problem with patient receptivity to the different colored barbiturates? A. Yes, I have.

Q. And have any patients ever refused to take the barbiturates because of the color change? A. I have had patients who have refused until they have discussed the matter with me and assured themselves that it was correct.

Q. After they spoke to you they had no problem; is that correct? A. I believe so.

Q. Have you ever prescribed in your practice an antidepressant called Amitriptyline hydrochloride? A. Yes.

Q. How would you prescribe that, by a brand name or otherwise? A. I prescribe that both ways, but most frequently I use the name Elavil.

[Tr. 883] Q. What color is that? A. It has three different colors depending upon the dosage size.

* * *

[Tr. 888] Q. Do you have a special person that buys drugs? A. Yes.

Q. Do you know what criteria they use? A. There is a list published by New York State of approved generic equivalents and from that list she chooses, I am sure, the least costly alternative.

Q. Is it your understanding that it is based upon costs? A. In the end, it is, yes.

Q. Do you know whether at the present time the source of the particular medication may be changed, namely one manufacturer one year, another the next year? A. No, the physicians wouldn't know that.

* * *

[Lipstein, Tr. 906] Q. Dr. Lipstein, would you recall that a suggestion was made that an alternative way to have acquired the names of persons throughout the United States who were users of Cyclospasmol would have been to make a telephone call.

Did you consider using that method? A. Well, a very rapid computation would demonstrate the outlandish and unreasonable nature of that kind of result. There are roughly 100,000 patients who are on Cyclospasmol. There are 80 million households in the United States. If one simply divides one by the other we get one in 800 people who are on Cyclospasmol.

To find 100 patients for interview purposes would have required identification or talking to [Tr. 907] 80,000 households.

THE COURT: Or 800.

THE WITNESS: From one in 800, it would turn it up to 80,000 multiplying it by 100.

Because of the incident rates we know in order to complete a single telephone interview one must make approximately six

dialings. So multiply the 80,000 times six gives us 480,000 dialings.

Number one, the cost of that would probably exceed a million dollars. But even more important than that is that I do not believe there is a single research company in the United States who could execute such a study.

Therefore, it is absolutely an unfeasable method of finding people who are on Cyclospasmol.

Q. Sir, if you did nonetheless go to this expense and make these telephone calls, how would you find out that the person to whom you are speaking is taking Cyclospasmol? A. You would have obviously to ask them if they take Cyclospasmol, in which case you would be conditioning them when you are inquiring as to Cyclospasmol, so having gone through the million dollar expenditure you [Tr. 908] would have destroyed the possibility of doing a study because you would have conditioned them.

* * *

[Tr. 915] THE COURT: So you just got those figures, the 80 per cent, what you figured out to 80 per cent or somebody did from Heller? A. Yes, that's right.

Q. And you didn't check out the figure? A. I had no time.

Q. That was not the question A. I was not able to check it out.

Q. One other question. Are there any other figures that you testified about that you personally haven't checked out? A. I did not do the interviewing myself.

Q. I am talking about the figures A. I reviewed the tabulations that came from the tabulation house. And all those figures which I thought were important to evaluate. I might say certainly that 80 per cent concerned me and I made inquiry about it.

[Bovoso, Tr. 929] Q. Mr. Bovoso, have you reviewed the chart identified as Premo — Plaintiff's Exhibit Premo 4? A. Yes.

Q. Have you prepared a chart which shows each instance of which you are aware in which the various generics come in colors different than the name brand shown on the chart? A. Yes.

Q. I show you Plaintiff's Exhibit 130. I ask, except for the last page of that exhibit, the exhibiit, in fact, shows or lists products that you know come in colors different from the name brand on the Stempel chart? A. Precisely.

Q. Could you tell us in how many instances there are available generics in non-look alike colors, from the chart? A. I would have to count them off here.

Q. Would you count them. I don't want to have to read it in.

(Pause)

A. 37 cases that are different.

Excerpts of Trial Proceedings

* * *

[Tr. 932] Q. When Smith, Kline sells generic products, do you know whether it uses any kind of identifying brand for its generic products? A. Sometimes they use generic names.

THE COURT: And sometimes another brand name?

THE WITNESS: If they want to call it that, I guess.

THE COURT: Another name, I should say.

Q. Looking at Exhibit 139, what is that? A. This is a picture chart of the products promoted by Smith, Kline and French in their generic SK line.

Q. Do you know if that is a current chart? A. It was February of '79. It is relatively current, to my knowledge.

Q. Have you made any attempt to determine whether Smith, Kline had products of a similar appearance in its generic line in 1977? A. Yes.

Q. How did you determine that? A. I compared this particular chart with the chart [Tr.933] that is listed in the 1977 PDR.

Q. I show you what has been marked Exhibit 137, Plaintiff's and I ask you if that is the book you used to make the determination?

(Exhibit shown to the witness.)

A. Yes, it is.

Q. What did you discover? A. That the list — this 1979 pictorial list of drugs is basically the same as it was in 1977 with a few additions to the 1970 — 1979 line.

Q. Do you know whether Smith, Kline judging from your review of the Physician's Desk Reference, and Exhbit [sic] 139 dropped any generic lines — generic products from its line? A. I could ascertain just one.

Q. Are you aware, Mr. Bovoso, of any studies done by any governmental organization in the State of New York concerning the substitution law in New York? A. Yes, the Attorney General's study done in conjunction with the Office of Consumer Affairs.

Q. I show you Exhibit 138 and I ask you if that is the study to which your're referring? A. Yes.

* * *

[Tr. 935] Q. In each instance where the reference is not in the PDR, do you have personal knowledge that the product referred to and the color referred to is, in fact, on the market? A. Yes.

Q. Looking at that same list, 130A, do you know how many of the products listed there can be considered long term medication — maintenance drugs? A. Yes, it would be easier enough to go down the list and pick them out.

Q. Could you do that quickly? A. Shall I name them or pick them out and give you an idea?

Q. Why don't you name Hydralazine. A. Hydralazine is one — cyclandelate is the next. Dexamethasone is often times used by arthritics. Amitriptyline, antidepressant. Hydrochlorothiazide, long term therapy.

* * *

[Tr. 940] Q. Were you always with Ives as a detail man? A. Yes.

Q. And is not the purpose of a detail man or detail person to go to a doctor and encourage the doctor to write specifically for the drug or the drugs of the company he works for? A. Yes, that is one of the purposes.

Q. Okay.

Now, with respect to Exhibit 139, which is the SK line, SK is Smith, Kline, is that correct? A. Smith, Kline & French.

Q. In Philadelphia? A. Yes.

Q. And they identify their drugs, do they not, with an SK; in other words, SK hydrochlorothiazide, SK Prednisolone, and SK-Prednisolone is not the generic name, the generic name is Prednisolone is that right? A. Yes.

Q. And SK details their drugs, do they not? A. Not to my knowledge. They do not detail this line of drugs.

Q. You specifically know they do not detail [Tr. 941] their drugs? A. I said not to my knowedge.

Excerpts of Trial Proceedings

Q. For a doctor to prescribe for SK, say hydrochlorothiazide, he would have to write as on this chart, SK hydrochlorothiazide? A. If a doctor specifically wanted the SK hydrochlorothiazide, yes.

Q. Okay.

With respect to Exhibit 134, MSD, Merck, Sharp & Dohme, they detail their drugs, do they not? A. Yes.

Q. And Abbott Labs details their drugs? A. Yes.

Q. And Ciba details its drugs? A. Yes, they do.

Q. And they all try to get the doctor to write for their specific brand of hydrochlorothiazide? A. I don't know that.

Q. Okay.

With respect to Amitriptyline hydrochloride, Hoffman LaRoche details its drugs, do they not? A. Yes.

Q. And Warner details its drugs, do they not? A. Yes.

Q. And U.S. Vitamin, on Imipramine, they [Tr. 942] detail their drugs, do they not? A. Yes.

I don't know if they specifically detail Imipramine.

Q. As far as you know they detail their drugs, is that right? A. Yes, they do.

Q. Papaverine hydrochloride, who is Saron? A. I have no idea.

Q. Central Pharmacy, have you ever heard of them? A. Only from picking the name out of a book, but I never saw them detail their product.

Q. How about Mayrand? A. I never saw them detail a product either.

Q. That was not the question I asked you.

I asked you who they were. A. I picked them out of a book.

Q. Marion. A. I think Marion Labs.

Q. And they detail their drugs, do they not? A. Yes, they do.

Q. Who is Key Pharmaceuticals, have you ever heard of them? [Tr. 943] A. Yes, I have.

Q. And what is the nature of their business? A. I think they detail. They vary, sometimes detailing and sometimes not detailing.

Q. Lemmon Pharmaceutical Company? A. Yes.

Q. They detail, don't they? A. I have never met a Lemmon representative.

Q. So you don't know if they do or they don't. A. That's right.

Q. Are you familiar with Savage Laboratories? A. No.

Excerpts of Trial Proceedings

Q. And Schering Laboratories, or Schering Plough I guess they are called? A. I know their sales people.

Q. They detail? A. Yes, they do.

MR. COBRIN: For the record, I am going through 130A.

Q. Warner/Chilcott details, do they not? A. I have met their sales people.

Q. Stuart Pharmaceuticals details, do they not? A. Yes, they do.

* * *

[Desiderio, Tr. 966] Q. And do you know approximately how many of the people who are entitled to use the out-patient facilities of the Medical Center are elderly? A. We have approximately 5,500 members who take advantage of our center, who are retired members of the industry, and they are over 65.

Q. Does the pharmacy at the Sidney Hillman Medical Center stock generics? A. We are 100 percent generic. Since we established the decision to go generic, it is at least ten years now.

Q. And do you know whether from time to time the pharmacy and the Sidney Hillman Medical Center has changed the source of a particular medication from one company to another. A. Yes.

* * *

Excerpts of Trial Proceedings

[Tr. 970] Q. Do you have the speciality, a speciality in your private practice, Doctor? A. Well, because of — I do internal medicine, but I have been taking care of people beyond the age of 65 for the last 15 years, I guess, ten or 15 years, and they comprise about 75 percent of my practice.

I have to say I have a special affinity for people in that age group.

Q. Have you also treated young people from time to time? A. Yes, I do.

Q. Do you have any opinion as to one age group manifests more confidence and reliance in the physician than another age group? A. My opinion is that the so-called geriatric population, particularly those above 70, have a greater reliance and a greater respect for th eopinion of the physician.

Q. Now, in your private practice had you ever had occasion, have you ever had an occasion when the color or the appearance of a drug was changed on a patient? A. Yes.

Q. And had you had inquiries as to that? A. Yes.

[Tr. 971] If a patient is hospitalized, and during this hospitalization he is given certain medication and on discharge his initial prescription is filled, and this happens when I refer a patient for in-patient therapy. And on leaving the hospital the prescription is filled for the first time at a neighborhood drug store. And then the patient comes to me at the center or comes to my office for a new prescription.

* * *

And in many instances — well, at times when the patient is discharged from the hospital for a prescription for digoxin, and I will change it to Lanoxin. And the patient will ask if it is the same [Tr. 972] as they received in the hospital. And I will say, yes, it is just a different company.

Q. And the patients generally accept the explanation? A. Yes.

* * *

Q. You say your hospital was 100 percent generic? A. We are not a hospital.

Q. The Sidney Hillman — A. Yes, the medical center.

Q. It is one hundred percent generic? A. Yes.

Q. Why is it generic as distinguished from brand names? A. We have a special prescription program for our retirees, whereby they pay one half the price — one half the cost of the prescription. And the maximum there that can be charged for any prescription is $2.00. So the Board of Directors, we have a peculiar Board of Directors, and they are involved, very well involved in the finances of our [Tr. 973] clinic, particularly since half of them are making contributions towards the support of the clinic. And we have quite an overhread in our pharmacy. And they want to convert it to the generic form to really save money so we will not go bankrupt.

* * *

Excerpts of Trial Proceedings

[Tr. 974] Q. So when Smith, Kline and French supplies your tetracycline it is always the same color because it comes from Smith, Kline and French; is that right? A. Yes. But before that we had the different color, the plain orange color, I think, from Squibb.

Q. Tetracycline is not a maintenance drug, is it? A. No, it's not a maintenance drug. But our biggest conversion was to switch from the Papaverine hydrochloride. When we switched from Cerespan to Papaverine we had a contract with Cerespan for at least three years and we switched to Papaverine.

Q. Doctor, has your office of the Sidney Hillman Foundation — the Sidney Hillman Medical Center, been visited by SKF detail men? A. Yes.

* * *

Q. Doctor, before a patient will come to you to tell you, to get reassured about a change in color, has the pharmacist first tried to convince him that he is getting the same drug? [Tr. 975] A. Yes.

Q. And apparently the patient does not accept the pharmacist's explanation when he comes to you? A. This is a rare occurrence.

Q. But it occurs? A. I have an image at our center that — this is not an ego session on my part, but the older people have a great of — we have a mutual love affair going on. All right. An 80 year old or many of the 80 year olds would come to the clinic mainly because I am there. It is difficult maybe for you to appreciate this love affair between me and my elderly patients, I

am sure. And some of them go to the extremes in this thing and say unless Dr. Desiderio says it I will not do it. This is not the unusual. This is the usual circumstance.

* * *

Q. What kind of product is this Papaverine you have just referred to? A. A maintenance drug for circulatory insufficiency, used for cerebral arterio insufficiency.

[Tr. 976] Q. You indicated in response to one of Mr. Cobrin's questions that you have been visited in the Center by detail men from Smith, Kline and French; is that right? A. Yes.

They come to my office as well as the pharmacy.

Q. Have they ever discussed their generic line? A. No.

* * *

Q. Has Smith, Kline and French ever left any literature to you about their generic line? A. No.

Q. Have you ever received any literature about their generic line? A. I don't.

Q. Has the pharmacy? A. He has a file about everything.

* *

[Kashickey, Tr. 983] Q. What do they do with the price list? A. Well, we get a solicitation from them. And we send a

price list to them, and if it meets with their approval, issue us an award.

So I have an installation who wishes to make a purchase can do so through this price list which has a contract number attached to it.

Q. Do you know whether the federal government takes steps to encourage pharmaceutical companies to enter into the bidding situation? A. Yes, they do.

If a particular item is within a company's price list and if it enjoys a pretty good movement, in other words, the VA or any one of the facilities, they purchase an awful lot of it, they will communicate, they will take the initiative and communicate with that company and try to enter into some sort of agreement, a negotiated contract.

When they do this, they will depot or stock inventory items at three locations throughout the United States, at any VA installation, Public Health Service Hospital, hospitals in Indian reservations, et cetera.

They can take advantage and purchase it from the depot.

Q. Now, to your knowledge, does there exist any [Tr. 984] federal government specifications in connection with the Cyclospasmol, cyclandelate, requiring it to be in a particular color? A. No.

Q. I now show you Exhibit 141 and ask you if you can identify it.

Excerpts of Trial Proceedings

MS. DRISCOLL: Your Honor, I have blocked out the price because of the confidentiality.

These are prices that Ives uses for bidding in government contracts.

THE COURT: Do you bid at a lower price than what you sell to the customer, to the ordinary consumer?

THE WITNESS: Sometimes, your Honor.

It depends on the quantities involved.

THE COURT: It would depend on quantities, whether in effect you give them a quantity discount.

THE WITNESS: To a degree.

We don't bid every single solitary item in our line.

Q. Can you identify Exhibit 141, Mr. Kashickey (handed to witness) A. This is one of the sheets of a solicitation [Tr. 985] that we have received from the Veterans Administration asking us to submit a quotation on Isosorbide nitrate, 40 milligrams.

* * *

[Tr. 986] Q. Now, have you ever sold Cyclospasmol cyclandelate to any state government? A. We do.

Q. And do you know whether there is any state which makes any reference to the color of the product to be purchased? A. Out of 50 states there is only one reference and that is the state of New Jersey.

Included in their solicitation is a reference that the color must be blue.

Q. Do you sell any of your Isordil to the State of New Jersey? A. Yes, I do.

Q. And do you know if Stuart Pharmaceutical Company sells Sorbitrate to the State of New Jersey? A. Yes.

Q. And are Isordil and Sorbitrate the same drug?

THE COURT: Do you mean the same chemical?

MS. DRISCOLL: Yes.

* * *

[Tr. 988] Q. And do you have any knowledge as to whether any of these local governmental agencies make any reference to color in connection with cyclandelate? A. No, they don't.

* * *

Q. As I understand your answer to Court's question, the bids list the drugs by generic name; is that correct? A. That's correct.

Q. Well, I notice that — do you prepare this information on the sheet 141? You type any of it in? A. Just — you know, the packing material and the unit price and the amount.

* * *

Q. Well, where it says Cyclospasmol under cyclandelate, who typed that in? A. That's the Veterans Administration.

[Tr. 989] Q. And they typed that in, do they not, so there is a reference for cyclandelate and they'll know what product they are talking about? A. That's right.

* * *

Q. Mr. Kashickey, to your knowledge, will the State of New Jersey accept a bid where the manufacturer offers cyclandelate in a color that's not blue? A. Judging from past history, with regard to our Isordil ten milligram, versus a Sorbitrate ten milligram, I would think that they would accept a bid from another manufacturer if the color was other than blue.

THE COURT: But they don't — they don't specify color as to that, do they?

THE WITNESS: They do in the State of New Jersey.

THE COURT: On your Isordil —

THE WITNESS: No, no. They don't specify it in the —

THE COURT: All right.

Q. Are you familiar with a federal standard for capsules for medicinal purposes? A. No, I am not.

* * *

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In The

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

DARBY DRUG CO., INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

JOINT APPENDIX

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Pursuant to Supreme Court Rule 30.6, two separate volumes of exhibits have been prepared. In accordance with the instructions of the Office of the Clerk, the second exhibit volume is reproduced in an oversized volume in order to accommodate the pictorial, graphic and other original matter contained therein. This table of contents lists the exhibits in the order in which they appear in the appendix. A separate combined index to exhibits appears in Volumes II and III.

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8*	Ives Package and Bottle of 200 mg. CYCLOSPASMOL Capsules, Physician Sample (Photograph Copy)	571a
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19B*	Title Page and Excerpt (p. 153) on CYCLOSPASMOL from Book entitled, "Prescription Drugs," by the Editors of CONSUMER GUIDE	573a
26*	One Individually Wrapped 400 mg. Capsule Labeled in Part "CYCLANDELATE 400 mg. CYCLOSPASMOL — CALVINSG⁹" (Photograph Copy)	576a
27*	One Individually Wrapped 400 mg. Capsule Labeled in Part "CYCLOSPASMOL (G) 400 mg." from Calvin's Drug Store (Photograph Copy)	576a
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104*	One Bottle from Carlysle Pharmacy, Dearborn, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	770a
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Inwood 6*	Excerpts from Publication of New York State Assembly's Office of Legislative Council entitled, "Are Generics Safe?", June 23-24, 1978	795a
Inwood 8*	Bottle and Capsule of Inwood Cyclandelate	831a
Inwood 9*	Capsules, 200 mg. and 400 mg. (Photographic Reproduction)	832a
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PLAINTIFF'S EXHIBIT 74 — A STUDY OF RECOGNITION AND CONFUSION OF DRUGS BY PRESCRIBERS AND USERS (JANUARY 1980)

A STUDY OF

RECOGNITION AND CONFUSION

OF DRUGS BY

PRESCRIBERS AND USERS

HHR

HARRY HELLER RESEARCH CORP.

* * *

Prepared for:

IVES LABORATORIES

By:

HARRY HELLER RESEARCH CORP.

HHR #X9624

January, 1980

BACKGROUND

It has been proposed that aside from the brand name, one of the major ways in which physicians and patients identify prescription drugs is by the color of the capsule.

Plaintiff's Exhibit 74

To quantify this hypothesis, this study was conducted among physicians who had prescribed and patients who had used Cyclospasmol recently and in the past. The goal of this study was to measure the extent to which both physicians and patients depend upon the color of Cyclospasmol in identifying it in a real life situation.

With hundreds of drugs heavily prescribed and used, the odds of identifying a specific drug as Cyclospasmol by chance is extremely small — unless the color of the capsule is the mode of identification.

SUMMARY

Among the physicians who prescribed Cyclospasmol 200 mg. dosage, 43% misidentified the generic blue capsules as Cyclospasmol. The bulk of them (28%) misidentified them spontaneously, while the remainder (15%) mididentified [sic] the blue capsules after seeing a list of ten drugs and associating the blue capsules with Cyclospasmol.

— The level of misidentification of the blue capsules as Cyclospasmol by physicians increases with the recency of Cyclospasmol having been prescribed by them. Among those physicians who prescribed Cyclospasmol within the past month, 60% misidentified the generic blue capsules as Cyclospasmol.

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	Physicians Who Prescribe 200 mg.				
	Total	Less Than One Month Ago	Less Than Six Months Ago	More Than One Month Ago	More Than Six Months Ago
Total Misidentification	43%	60%	49%	22%	20%
Spontaneously misidentified Blue/capsules as Cyclospasmol	28	40	33	13	10
Misidentification of Blue capsules as Cyclospasmol after seeing list of 10 drug brands on card	15	20	16	9	10
Did not identify Blue capsules as Cyclospasmol	57	40	51	78	80
Sample Size	(53)	(30)	(43)	(23)	(10)

Of those who prescribed the 400 mg. dose of Cyclospasmol, 20% misidentified the generic blue/red capsules as Cyclospasmol.

Plaintiff's Exhibit 74

— Again, the level of misidentification of the blue/red capsules as Cyclospasmol increased among physicians who prescribed the drug within the past month (31% misidentified the generic blue/red capsules as Cyclospasmol.

	Physicians Who Prescribed 400 mg.				
	Total	Less Than One Month Ago	Less Than Six Months Ago	More Than One Month Ago	More Than Six Months Ago
Total Misidentification	20%	31%	24%	5%	-%
Spontaneously misidentified Blue-Red capsules as Cyclospasmol	12	21	14	-	-
Misidentification of Blue/Red capsules as Cyclospasmol after seeing list of 10 drug brands on card	8	10	10	5	-
Did not identify Blue/Red capsules as Cyclospasmol	80	69	76	95	100
Sample Size	(50)	(29)	(42)	(21)	(8)

Plaintiff's Exhibit 74

Among patients for whom the 200 mg. dose of Cyclospasmol was prescribed, 67% misidentified the generic blue capsules as Cyclospasmol with 50% of all patients spontaneously misidentifying the blue capsules as Cyclospasmol.

— Since it was found that not all the patients were aware of name of the drug prescribed by their doctor (Cyclospasmol), the group of patients who were aware of the name Cyclospasmol were analyzed separately. Among patients aware of the name Cyclospasmol, 92% misidentified the generic blue capsules as Cyclospasmol with 69% making a spontaneous misidentification.

Among patients for whom Cyclospasmol was prescribed in the 400 mg. dosage, 67% misidentified the generic blue/red capsules as Cyclospasmol.

— Again, among patients who were aware of the name Cyclospasmol, 100% misidentified the blue/red capsules as Cyclospasmol.

Plaintiff's Exhibit 74

	Patients					
	Had 200 mg.		Prescribed	Had 400 mg.		Prescribed
	Total	Know Cyclospasmol Prescribed	Don't know Cyclospasmol Prescribed	Total	Know Cyclospasmol Prescribed	Don't know Cyclospasmol Prescribed
Total Misidentification	67%	92%	-	67%	100%	14%
Spontaneously misidentified Blue or Blue/Red capsules as Cyclospasmol	50	69	-	17	27	-
Misidentification of Blue or Blue/Red capsules as Cyclospasmol after seeing list of ten drug brands on card	17	23	-	50	73	14
Did not identify Blue or Blue/Red capsules as Cyclospasmol	33	8	100	33	-	86
Sample size	(18)	(13)	(5)	(18)	(11)	(7)

Plaintiff's Exhibit 74

When physicians and patients were asked their criteria for identification of a drug, the dominant determining factor for both groups was the color of the capsules.

— Among physicians, 52% said color was the determining factor.

— Among patients, 79% said they used color to make their identification.

(See Tables 1 and 10)

Sampling Errors at the 80% Significance Level for Various Sample Sizes and Percentage

	Sample Sizes					
Percentages*	10	20	30	50	75	100
10% or 90%	12%	9%	7%	5%	4%	4%
20% or 80%	16	11	9	7	6	5
30% or 70%	18	13	11	8	7	6
40% or 60%	20	14	11	9	7	6
50%	20	14	12	9	7	6

* These estimates of sampling error imply that if the sample were re-drawn repeatedly and independent estimates derived, that 80% of the time the observed percentages would fall within the sampling errors given in the table above.

Plaintiff's Exhibit 74

APPENDICES

Appendix A — Tables for Physicians

Appendix B — Tables for Patients

Appendix C — Method

APPENDIX A

TABLES FOR PHYSICIANS

Table 1

Method by Which Drugs Were Identified

	Total
Color	52%
Prescribe them/take myself	38
Capsule has name on it	32
Seen it before	20
Granules/spanules	15
Size	12
Have seen samples	11

Plaintiff's Exhibit 74

I take them myself	10
Shape	8
Manufacturer's Trademark	7
Other reasons	6
Base: Physicians who recognized at least one capsule	(82)

Table 2

Spontaneous Recognition of Any of the Four Colored Capsules

	Total
Yes	85%
No	15
Base: Total	(96)

Table 3

Spontaneous Recognition by Color

	Total
Recognize all blue	35%
Recognize blue/red	21

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Recognize brown/white	89
Recognize maroon/white	92
Base: Physicians who recognized at least one capsule	(82)

Table 4

Correct Spontaneous Recognition by Color Based Upon Claimed Recognition

	Total	Base
All blue (misidentified as Cyclospasmol)	59%	(29)
Blue/Red (misidentified as Cyclospasmol)	47	(17)
Brown/White (identified as Pavabid)	95	(73)
Maroon/White (identified as Dyazide)	88	(75)

Plaintiff's Exhibit 74

Table 5

Ever Prescribed Cyclospasmol

	Total
Yes	93%
No	7
Base: Total	(96)

Table 6

Last Time Cyclospasmol Prescribed

	Total
Less than one month ago	52%
1 - 3 months ago	17
Between 3 and 6 months ago	9
More than 6 months ago	22
Base: Total	(89)

Plaintiff's Exhibit 74

Table 7

Dosage of Cyclospasmol Prescribed

	Total
200 Milligrams	40%
400 Milligrams	37
Both	20
Base: Total	(89)

Table 8

Medical Specialty of Physician

	Total
General family practitioner	53%
Internist	25
Podiatry	8
Surgeon	4
Diagnostician	2
Ear, nose, & Throat	1
Rheumatologist	1

Plaintiff's Exhibit 74

Physician (D.O.)	1
Gynocologist	1
Pulmonary medicine	1
Geriatrics	1
E.G.	1
Base: Total	(96)

Table 9

Percent of Patients Over 65 Years of Age

	Total
Less than 20% over 65	14%
20% - 39%	47
40% - 59%	19
60% - 79%	15
80% Or More	5
Base: Total	(96)

Plaintiff's Exhibit 74

APPENDIX B

TABLES FOR PATIENTS

Table 10

Method by Which Drugs Were Identified

	Total
Color	79%
Size	25
Looks like one I take	14
Shape	11
Has word written on it	7
Looks like one I used to take	4
Base: Patients who recognized at least one capsule	(28)

Plaintiff's Exhibit 74

Table 11

Aware That Cyclospasmol is Prescribed for Them

	Total
Aware of Cyclospasmol	67%
Unaware of Cyclospasmol	33
Base: Total	(36)

Table 12

Length of Time Taking Cyclospasmol

	Total
One month or less	11%
Two - six months	28
Nine months - year	11
More than one year	31
No longer taking	8
Not sure	11
Base: Total	(36)

Plaintiff's Exhibit 74

Table 13

Number of Capsules Taken Per Day

	Total
One	14%
Two	36
Three	8
Four	22
Not sure	20
Base: Total	(36)

DESCRIPTION OF DRUG POSSESSED BY PATIENTS

Table 14

Is Name Printed on Capsule?

	Total
Name is Printed On Capsule	58%
Ives	50
Upjohn	3
Premo	3
NC	3

Plaintiff's Exhibit 74

Name is Not Printed on Capsule	14
No Capsules Left to Examine	28
Base: Total	(36)

Table 15

Is Number Printed on Capsule?

	Total
Yes	53%
No	19
No capsules left to examine	28
Base: Total	(36)

Table 16

Color of Capsule

	Total
Blue/red	39%
Blue	25
Clear and Black	6
Red	3

Plaintiff's Exhibit 74

Maroon and red	3
No capsule left to examine	28
Base: Total	(36)

Table 17

Do All Capsules Have Same Markings?

	Total
Yes	67%
No	5
No capsules left to examine	28
Base: Total	(36)

Table 18

Age of Patients

	Total
20 - 49	6%
50 - 59	14
60 - 69	33
70 or older	47
Base: Total	(36)

Plaintiff's Exhibit 74

METHOD

The original design of the study was to interview approximately 100 physicians who had prescribed Cyclospasmol for their patients and obtain the names of 100 patients who had used Cyclospasmol as a result of the doctor's prescription. The interview was structured to provide both physicians and patients with a variety of drug products and to determine the extent to which they identify a blue or blue/red capsule as Cyclospasmol. This information was obtained in two ways — spontaneously and by association with a list of 10 drug products.

In this study, products were used that looked like the 200 mg and 400 mg forms of Cyclospasmol to determine recognition and confusion.

The Sample

In designing the sample for this study, a variety of controls were exercised.

1. All physicians chosen in the study must have had some experience in the past with Cyclospasmol.

2. The sample of physicians selected must be representative of the total population of physicians who could prescribe Cyclospasmol.

3. Several attempts must be made to contact the specific physician selected in order to represent the sample properly.

Plaintiff's Exhibit 74

Only by following these three rules would the final sample of approximately 100 physicians be representative of the total population of Cyclospasmol prescribers in the U.S.

A. The Sampling Frame

The "frame" from which the sample was selected consisted of a list of approximately 12,000 physicians ordered by Zip Code. These were identified by Ives detail persons as having prescribed Cyclospasmol for their patients. The exact nature of their prior behavior was not pre-determined. While the exact history of each physician on the list in prescribing Cyclospasmol was not known, this group of physicians was the best representation of doctors who was believed to have prescribed Cyclospasmol.

During the course of the study a specific question was asked to determine the extent to which the sample had prescribed Cyclospasmol.

B. Selection of the Sample from Within the Frame

Before the sample was selected, several considerations were made which affected the way in which the sample was selected.

1. It was decided that the sample would be selected from among 20 sampling points spread throughout the U.S. This was done to provide for five interviews within each sampling point and to represent a wide variety of geographical locations in the sample of physicians and to insure that the selection of each physician would not be left to the discretion of the interviewer.

Plaintiff's Exhibit 74

2. The specific areas used for the study were chosen randomly. When an area was chosen that did not have an adequate number of prescribing physicians available, an immediately adjacent area was selected.

   Pre-testing had demonstrated the exceedingly great difficulty in executing the study. It was clear that the very best trained interviewers were required for sound execution of the project. In 1 or 2 cases where an initially selected area did not have such qualified interviewers, an immediately adjacent area was selected. The areas used in the survey are listed on the next page.

AREAS USED

Portland, ME

New York City, NY

Syracuse, NY

Pittsburgh, PA

Washington DC Area

Charlotte, NC

Atlanta, GA

Miami Area

Memphis, TN

Plaintiff's Exhibit 74

Louisville, KY

Dayton, OH

Omaha, NE

Peoria, IL

Kansas City, MO

New Orleans, LA

Dallas, TX

San Antonio, TX

Los Angeles Area

San Francisco, CA

Seattle, WA

3. Once the specific area was selected, the names of physicians within that area were listed and sent with the interviewing materials to the interviewers. Interviewers were instructed to make several attempts to make appointments with the physicians on the list until the assigned interviews were completed within reasonable distance and travelling time.

C. Random Method of Selecting Interviewing Areas

To select the sample, a random number was selected from a table of random numbers by Dr. Benjamin Lipstein. This

Plaintiff's Exhibit 74

number identified the first physician and area which was selected. Based upon the total length of the list, a skip pattern of 602 names was specified (602 X 20 - 12,040). This procedure yielded 20 geographical areas each described by a cluster of physicians. Each of the 20 areas was examined to determine if enough physicians were available. Then if skilled interviewers were available in the area it was chosen. The nature of this random selection resulted in a geographical stratification by zip codes which increases the statistical reliability of the results.

Since interviewing was conducted during the month of December 1979, several areas were selected for which interviewers were available, but unable to take the assignment due to other market research work done during this time period and a shortage of demonstration materials. These areas are being completed during the month of January. Their results will be combined with these.

D. The Interview

1. Physicians

As a starting point, interviewers telephoned a randomly selected physician on the list in the cluster and made an appointment with the physician for an office visit. This initial call introduced the research in a non-specific manner and offered the physician payment of his normal fee for the office visit. Several telephone calls were made to properly represent the physicians to be selected in the sample. Specific instructions were given the interviewer to respond in a general way to answer any questions that the physician may have brought up in the course of setting the appointment.

Plaintiff's Exhibit 74

In the event that a physician refused to cooperate on the survey, the interviewer was instructed to choose the next name on the list. If all physicians in the area were exhausted, a neighboring area and group of physicians were selected.

During the appointment, the interviewer re-introduced him or herself and asked the doctor:

a. His medical specialty
b. The percentage of his patients over 65 years of age

Physicians were told that they would be talking about medication that can be prescribed for some elderly people. Four different capsules were spread on the desk between the interviewer and the physician. The doctors were asked whether they recognized any of the capsules and if so, to separate and identify the capsules that they are familiar with.

Included in the group of capsules were three blue capsules the color of Cyclospasmol 200 mg. (2 unmarked and 1 marked Premo), three blue and red the color of Cyclospasmol 400 mg. (2 unmarked and 1 marked Premo), three brown and white capsules the color of Pavabid (one marked Pavabid, one marked centrol and one unmarked), and three maroon and white capsules the color of Diazide (all 3 marked Diazide). Physicians were asked how they recognized the capsules they separated and to name each of the products that they had separated.

In the event that the physician was not able to spontaneously associate the capsules by color to Cyclospasmol in either the 200 mg. or 400 mg. form,

the physician was given a card with a list of 10 drug products on it. The list consisted of Cyclospasmol, Pavabid and Diazide and 7 other drugs selected at random from a list of the 200 largest selling drugs. (The list on the cards was rotated so that each drug appeared in each position an equal number of times). The physician was shown the card and asked whether they can now associate any of the capsules, and if so, to identify the capsule or capsules he could identify.

After this phase of the interview, the doctor was asked whether he had ever prescribed Cyclospasmol, when was the last time he had prescribed Cyclospasmol, and what dosage of Cyclospasmol he had prescribed in the past.

In order to obtain patients for the second phase of the study, the physicians were asked to supply the interviewer with the names and addresses of any patients for whom the doctor had prescribed Cyclospasmol and the dosage in which it was prescribed. The physician was reassured that the purpose of this survey was to learn how patients recognize certain capsules and nothing to do with professional treatment in the prescription. He was also asked not to communicate to the patient anything about the study. He was told that the patient would be paid a fee for the interview and he or his nurse was offered a reimbursement for supplying the names of the patients who were willing to cooperate.

Plaintiff's Exhibit 74

2. The Patient Interview

To start, the interviewer introduced herself to the patient and offered the patient a $10.00 fee for the interview. The first question asked the patient was whether his doctor had called about the interview and what the doctor or nurse said about the interview. Two sets of 3 prescription bottles each were available in the interview and depending upon whether the patient was a 200 mg. or 400 mg. user of Cyclospasmol, a set was selected for that respondent. In each set of 200 mg. products, one bottle was labelled Cyclandelate Inwood, one Cyclandelate Premo, and one Cyclandelate MD. One bottle in each set of 400 mg. was labelled Cyclandelate Inwood, one Cyclandelate Premo, and one Cyclandelate Rugby.

Capsules in the Premo bottles were imprinted with the name "Premo". All of the others were unmarked. The 3 prescription bottles were placed on the table in front of the respondent. Each of these bottles had a different closure system and the patient was asked to open the bottles and place the cap next to the bottle.

After the bottle was opened, the patient was asked whether he or she recognized the capsules in each of these bottles, and if so, how were they recognized, and what the name of the medication was. In the event that the patient did not spontaneously associate the color of the capsule with the Cyclospasmol dosage he or she was taking, a card listing 10 drugs was presented to the patient and the patient asked whether any of the capsules in the bottles were any of the drugs on the list.

Plaintiff's Exhibit 74

This list contained Cyclospasmol and 9 randomly selected drugs from a list of the 200 leading drugs. Then the patient was asked whether the doctor had ever prescribed Cyclospasmol or whether the doctor had prescribed a medication that looks like that.

Next, the interviewer asked the patient to see the actual medication the doctor had prescribed for him or her that looks like the medication in the bottles shown to the patient. Where the interview determined that the prescription was marked Cyclospasmol and did not actually contain capsules on which Ives appeared, the interviewer was asked to contact our office through her immediate supervisor. All information about their specific used of Cyclospasmol was obtained including background information, how long the medication has been taken, how many capsules were taken daily and the age of the patient.

VALIDATION

In order to determine that the interviews were administered according to the specifications of the study, an independent company validated, for each interviewer who worked on the project, one physician questionnaire and one patient questionnaire.

Validation consisted of calling the interviewees and determining that the key sections of the interview were administered correctly and in the proper sequence.

Plaintiff's Exhibit 74

Non-used Interviews

As part of Heller Research's internal validation of questionnaires, it was found that six patient interviews were administered improperly; that is, all questions were not asked that should have been asked. The data from these questionnaires were eliminated from the analysis. This is standard procedure in market research studies.

PLAINTIFF'S EXHIBIT 75 — UPDATE AND SUMMARY ANALYSIS OF EXHIBIT 74

SUMMARY

Among the physicians who prescribed Cyclospasmol 200 mg. dosage, 40% misidentified the generic blue capsules as Cyclospasmol. The bulk of them (24%) misidentified them spontaneously, while the remainder (16%) misidentified the blue capsules after seeing a list of ten drugs and associating the blue capsules with Cyclospasmol.

— The level of misidentification of the blue capsules as Cyclospasmol by physicians increases with the recency of Cyclospasmol having been prescribed by them. Among those physicians who prescribed Cyclospasmol within the past month, 55% misidentified the generic blue capsules as Cyclospasmol.

Plaintiff's Exhibit 75

	Physicians Who Prescribe 200 mg.				
	Total	Less Than One Month Ago	Less Than Six Months Ago	More Than One Month Ago	More Than Six Months Ago
Total Misidentification	40%	55%	46%	21%	15%
Spontaneously misidentified Blue/capsules as Cyclospasmol	24	34	28	10	8
Misidentification of Blue capsules as Cyclospasmol after seeing list of 10 drug brands on card	16	21	18	10	8
Did not identify Blue capsules as Cyclospasmol	60	45	54	79	85
Sample Size	(67)	(38)	(54)	(29)	(13)

Plaintiff's Exhibit 75

Of those who prescribed the 400 mg. dose of Cyclospasmol, 23% misidentified the generic blue/red capsules as Cyclospasmol.

— Again, the level of misidentification of the blue/red capsules as Cyclospasmol increased among physicians who prescribed the drug within the past month (31% misidentified the generic blue/red capsules as Cyclospasmol.

	Physicians Who Prescribed 400 mg.				
	Total	Less Than One Month Ago	Less Than Six Months Ago	More Than One Month Ago	More Than Six Months Ago
Total Misidentification	23%	31%	25%	12%	10%
Spontaneously misidentified Blue-Red capsules as Cyclospasmol	11	20	14	-	-
Misidentification of Blue/Red capsules as Cyclospasmol after seeing list of 10 drug brands on card	11	11	12	12	10
Did not identify Blue/Red capsules as Cyclospasmol	77	69	75	88	90
Sample Size	(61)	(35)	(51)	(26)	(10)

Plaintiff's Exhibit 75

Among patients for whom the 200 mg. dose of Cyclospasmol was prescribed, 67% misidentified the generic blue capsules as Cyclospasmol with 52% of all patients spontaneously misidentifying the blue capsules as Cyclospasmol.

— Since it was found that not all the patients were aware of name of the drug prescribed by their doctor (Cyclospasmol), the group of patients who were aware of the name Cyclospasmol were analyzed separately. Among patients aware of the name Cyclospasmol, 93% misidentified the generic blue capsules as Cyclospasmol with 73% making a spontaneous misidentification.

Among patients for whom Cyclospasmol was prescribed in the 400 mg. dosage, 73% misidentified the generic blue/red capsules as Cyclospasmol.

— Again, among patients who were aware of the name Cyclospasmol, 100% misidentified the blue/red capsules as Cyclospasmol.

Plaintiff's Exhibit 75

	Patients					
	—Had 200 mg. Prescribed—			—Had 400 mg. Prescribed—		
	Total	Know Cyclo-Spasmol Pre-cribed	Don't know Cyclo-spasmol Pre-cribed	Total	Know Cyclo-spasmol Pre-cribed	Don't know Cyclo-spasmol Pre-scribed
Total Misidentification	67%	93%	-	73%	100%	14%
Spontaneously misidentified Blue or Blue/Red capsules as Cyclospasmol	52	73	-	27	40	-
Misidentification of Blue or Blue/Red capsules as Cyclospasmol after seeing list of ten drug brands on card	14	20	-	45	60	14
Did not identify Blue or Blue/Red capsules as Cyclospasmol	33	7	100	27	-	86
Sample size	(21)	(15)	(6)	(22)	(15)	(7)

PLAINTIFF'S EXHIBIT 79 — REPLICATION SAMPLE OF PATIENTS (SUPPLEMENTAL ANALYSIS)

REPLICATION SAMPLE OF PATIENTS

A separate sample of 28 patients recruited by random dialings to doctors to obtain names of patients to whom Cyclospasmol was prescribed was obtained.

Among patients for whom the 200 mg. dose of Cyclospasmol was prescribed (small base) 50% spontaneously misidentified the generic blue capsules as Cyclospasmol.

Among patients for whom Cyclospasmol was prescribed in the 400 mg. dosage, 75% misidentified the generic blue/red capsules as Cyclospasmol.

— Among patients who were aware of the name Cyclospasmol, 93% misidentified the generic blue/red capsules as Cyclospasmol with 60% of those patients making a spontaneous misidentification.

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Replication Sample of Patients

	Patients					
		Had 200 mg. Prescribed		Had 400 mg. Prescribed		
	Total	Know Cyclospasmol Prescribed	Don't know Cyclospasmol Prescribed	Total	Know Cyclospasmol Prescribed	Don't know Cyclospasmol Prescribed
Total Misidentification	50%	-%	50%	75%	93%	44%
Spontaneously misidentified Blue or Blue/Red capsules as Cyclospasmol	50	-	50	46	60	22
Misidentification of Blue or Blue/Red capsules as Cyclospasmol after seeing list of ten drug brands on card	-	-	-	29	33	22
Did not identify Blue or Blue/Red capsules as Cyclospasmol	50	-	50	25	7	56
Sample size	(4)	(0)	(4)	(24)	(15)	(9)

PLAINTIFF'S EXHIBIT 83 — A STUDY OF PRESCRIPTION FILLING AND LABELING BY PHARMACISTS IN NEW YORK STATE

A Study of

Prescription Filling and Labelling

by Pharmacists

in New York State

Prepared for:

Ives Laboratories

by

Benjamin Lipstein, Ph.D.

BACKGROUND

Cyclospasmol is a branded vasodilator drug distributed by Ives Laboratories. A generic form of this drug called Cyclandelate has been manufactured and distributed by a number of drug companies.

It is the belief of the Ives management that prescriptions written by physicians for Cyclospasmol are on occasion filled properly

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by pharmacists with the generic drug, but that the generic is labeled as Cyclospasmol.

The purpose of this study was to determine if pharmacists in New York State fill prescriptions for Cyclospasmol with the generic drug, but conceal this practice from the purchaser (patient) through labeling of the drug container with the brand name Cyclospasmol.

FINDINGS

Randomly selected samples of pharmacists from both the Ives list of pharmacists believed to carry Cyclospasmol and the generic Cyclandelate and randomly selected pharmacists from the *Hayes Directory* were given a prescription for 200 mg. or 400 mg. of Cyclospasmol by the shopper and asked to fill the prescription. The prescription did not require that the brand name must only be dispensed. The pharmacists filled these prescriptions in their normal way.

Of the 42 pharmacists from the Ives list who were able to fill the prescription, 57% (24 pharmacists) executed it with the branded product, Cyclospasmol. Cyclandelate was used to fill the Cyclospasmol prescriptions by 18 pharmacists (43%). In twelve of the eighteen cases the prescription container was labeled with the name Cyclandelate and in the other 6 cases the prescription bottle was labeled with the brand name Cyclospasmol. Thus, of the 18 pharmacists who dispensed generic Cyclandelate, 33% labeled the prescription container with the brand name Cyclospasmol.

The results of the prescription fulfillment among the sample of pharmacists from the *Hayes Directory* were substantially the

same as from the Ives list. Of the 41 pharmacists, who filled the prescription, 58% (24 pharmacists) used the branded product Cyclospasmol and labeled it as Cyclospasmol. Forty-two percent of the pharmacists (17 pharmacists) used the generic Cyclandelate in fulfilling the prescription. Of the 17 pharmacists, 13 pharmacists labeled it with the generic name Cyclandelate and the other 4 pharmacists labeled it with the brand name Cyclospasmol. Thus, of the 17 pharmacists who dispensed generic Cyclandelate, 24% labeled the prescription container with the brand name Cyclospasmol.

Since the two samples of pharmacists were selected from two different lists, one from a group of pharmacists identified by the Ives sales force as carrying both the branded product Cyclospasmol and generic Cyclandelate and the other form the list of drug stores in the *Hayes Directory* with no information on whether or not they carried Cyclospasmol and generic Cyclandelate, the question arises, "Are the two sets of results statistically equivalent?" and "Should both sample results be combined for an overall view of prescription fulfillment in New York State?".

Statistical analysis of these two independent samples shows that all the percentages for the equivalent estimates are not statistically different. Namely, the 57% estimate of prescription fulfillment with Cyclospasmol is not statistically different from the equivalent estimate of 58% estimated from the *Hayes Directory* sample. The same is true for the 43% and the 42% estimates for fulfillment with Cyclandelate.

On the basis of this statistical analysis it is sound and proper to combine both sample results. This provides a sample base of 83 pharmacists, 58% (48 pharmacists) who filled the prescriptions

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with the branded product Cyclospasmol, and 42% (35 pharmacists) who filled the prescription with Cyclandelate. Twenty-nine percent (10 pharmacists) of the prescription containers filled with Cyclandelate were labeled Cyclospasmol.

Ives List of Pharmacies

Prescription Fulfillment by Pharmacists

	Number	Percent
Cyclospasmol dispensed	24	57
Cyclandelate dispensed	18	43
Total	42	100

Prescription Labeling

When Cyclandelate Dispensed By Pharmacists

	Number	Percent
Cyclandelate dispensed and labeled Cyclandelate	12	67
Cyclandelate dispensed and labeled as Cyclospasmol	6	33
Total	18	100

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Hayes Directory List of Pharmacies

Prescription Fulfillment by Pharmacies

	Number	Percent
Cyclospasmol dispensed	24	58
Cyclandelate dispensed	17	42
Total	41	100

Prescription Labeling

When Cyclandelate Dispensed By Pharmacists

	Number	Percent
Cyclandelate dispensed and labeled Cyclandelate	13	76
Cyclandelate dispensed and labeled as Cyclospasmol	4	33
Total	17	100

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Total Combined Sample of Pharmacies

Prescription Fulfillment by Pharmacists

	Number	Percent
Cyclospasmol dispensed	48	58
Cyclandelate dispensed	35	42
Total	83	100

Prescription Labeling

When Cyclandelate Dispensed By Pharmacists

	Number	Percent
Cyclandelate dispensed and labeled Cyclandelate	25	71
Cyclandelate dispensed and labeled as Cyclospasmol	10	29
Total	35	100

METHODOLOGY

Since pharmacists are licensed by individual states, it was decided to investigate this issue of prescription fulfillment within the bounds of New York State. From sales and field experience, the Ives sales force had observed that some pharmacies in the

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state apparently carried the generic product Cyclandelate as well as the branded product Cyclospasmol. Based upon this information, the sales force was requested to provide a list of pharmacies in New York State which carried both Cyclospasmol and the generic product Cyclandelate. This list of pharmacies consisted of four hundred thirty two pharmacies, identified by name, address and zip code.

The pharmacies identified as carriers of both products were entered on to a computer which provided a listing of the pharmacies by zip code. Using a random start, groups of four pharmacies were selected from the list on a systematic basis. This sampling provided a random sample of fifty-two pharmacies from the list of pharmacies known to carry both the branded product and its generic form.

However, based upon *Hayes Druggist Directory,* 1979 edition, there were approximately three thousand druggists in the state of New York. No information was available on whether or not they carried either Cyclospasmol or the generic equivalent Cyclandelate. In order to arrive at an objective determination of prescription fulfillment, it was decided to select an independent sample of pharmacies from the directory. The New York State part of the directory is to be found on pages 382 to 434 inclusive. Since the druggists in the *Hayes Directory* are grouped by minor civil divisions, the slection [sic] of the sample of druggist by page would automatically provide excellent geographic distribution throughout the state. For each page of the directory related to New York State, a two digit random number was selected. Starting at the top of each page, the druggists where [sic] counted until the random number was reached. This determined the sample druggist for further study.

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Prescriptions for 200 mg. and 400 mg. of Cyclospasmol were obtained from physicians in the area of the selected pharmacies. Shoppers were engaged to visit each of these pharmacies for the purpose of having the pharmacist fill the specific prescription. In total, 83 pharmacies filled the prescription, 42 from the Ives list and 41 from the *Hayes Directory*. Twenty-three stores were either out of stock or did not stock the particular drug, were out of business or were not a retail pharmacy. These fulfilled prescriptions were then sealed by the investigator, placed in a special envelope with information on the name of the pharmacy, its address and the amount paid for the prescription and sealed. These sealed envelopes were delivered in person to Dr. Benjamin Lipstein and/or to Rogers, Hoge & Hills which firm then redelivered them unopened to Dr. Lipstein. Dr. Lipstein personally opened each envelope and prescription bottle and made the calculations contained in this report.

PLAINTIFF'S EXHIBIT 123 — REMARKS OF DR. EDWARD STEMPEL, 1960

* * *

SHOULD STATE BOARD IDENTIFICATION EXAMINATIONS BE ELIMINATED?

College requirements have influenced the curriculum content of the secondary school programs that are offered to students who plan to attend college. In like fashion, the contents of state board licensing examinations in pharmacy have influenced the teachings in the pharmaceutical curriculum.

Many a pharmacy educator may have asked the question, "Are we training students to pass licensing examinations or are we providing an education for practicing the profession of pharmacy?" I believe that education for careers in pharmacy is in accord with the modern philosophy of pharmaceutical education. Nevertheless, perhaps some educators harbor the thought that their educational endeavors are sometimes fruitless if the student cannot have a career in retail pharmacy because of his failure to pass the state licensing examination. Therefore, some educators may be influenced to some small extent by the contents of pharmacy licensing examinations. Perhaps this article can motivate some board members to remove from state licensing examinations what many educators consider an annoying and dangerous influence, specifically, the identification examination.

The identification examination is a recognition test. As Gable[1] pointed out at the 1958 District No. 2 meeting, the recognition test attempts to measure the individual's ability to recognize essential characteristics of a product or to identify objects such as botanical specimens. Katz[2] stated that the

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Pennsylvania identification examination is given by means of a matching-type examination whereby the names of the items are provided and must be matched with the appropriate numbered specimens. Vitale[3] said that the New Jersey identification examination requests the candidate to provide the names of the 10 items presented by the examiners; these items consist of 8 capsules or tablets and 2 liquids. The New York identification examination is similar to that of New Jersey; some recent New York identification examinations (1959 and 1960) asked the candidate the names of 6 to 7 capsules or tablets, 2 to 3 official liquids, and one botanical specimen. From letters received from other states in District No. 2, it was learned that Delaware "has no set rule for the examination of specimens, and it is a matter left entirely to the examiner who lately has asked for the identification of 20 specimens," while the District of Columbia, Maryland, Virginia, and West Virginia do not have identification examinations.

Many pharmaceutical dosage forms may vary in certain physical properties, such as color, odor, and taste. Capsules and tablets may, in addition, vary in other physical properties, i.e., have various shapes, may be plain or lettered (with the letters raised or indented), or show a special design[4] in order to convey a characteristic identification. The variety in the physical appearance of many pharmaceutical dosage forms provides for esthetic appeal, psychological satisfaction, and a possible deterrent to the problem of substitution. *Scoville's The Art of Compounding*[4] states that some manufacturers have developed unusual shapes for tablets in order to obtain a distinctive product and to make duplications (and possible substitution) of their tablet more difficult. Lascoff[5] likewise points out that identifying symbols or letters on tablets and capsules is an attempt to curb substitution, which has plagued some manufacturers at one time or another.

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Some pharmacists believe that identification by physical appearance is advantageous in many instances; however, I do not agree.

Older pharmacists have stated that the physical properties of certain pharmaceuticals have provided the pharmacist who has erred in the initial reading of the label of the container with another opportunity to recognize his mistake. However, I believe that careful rechecking of the label of the container would provide the pharmacist with the same opportunity.

An older pharmacist tells the story of a reputable chemical house that made a mistake about thirty years ago in labeling a filled container, and the retail pharmacist using the contents recognized that the contents could not be what the label represented it to be. It is difficult to believe that today, in 1960, reputable manufacturers, with their excellent systems of control procedures, could possibly err in labeling the containers.

An employee indoctrination book issued by the Fidelity Prescription Stores in Cleveland provides as one of their seven "tips and reminders" that the pharmacist verify the physical appearance to see whether the color, odor, shape, or other physical property of the tablet, capsule, or powder is correct.[6] I would like to point out that an individual cannot verify what he has not seen previously; therefore, the Fidelity "tip and reminder" concerning the checking and rechecking of the label of the container, [6] that should always be practiced, is far more valid.

Lascoff's column on "Prescription Problems" states[7] that a pharmacist writes, "To an increasing extent, physicians in our area have been sending us tablets, prescribed for one of their patients by some other physician, for the purpose of

identification. . . . one physician sent us three different tablets. Fortunately, one was readily identified because it was a Smith Kline and French product which we could pin down immediately from the identification chart in their catalogue. . . . Don't you think all manufacturers could render a real service by putting identification charts in their catalogues?" The question in Lascoff's column was answered exceedingly well by a Pennsylvania pharmacist[8] who replied, "One of our primary responsibilities, as pharmacists, is the filing of all prescriptions. This information is then available to any authorized person desiring it. The *only* possible way to definitely establish the identify of a prescribed drug is through the prescription files of the dispensing pharmacist. Any attempt to identify a drug wholly by its physical characteristics, aside from being time-consuming, can be hazardous, and this procedure should be discouraged."

Lascoff[5] has stated, ". . . recently a child's life was saved by the quick identification by a pharmacist of some tablets which had been swallowed by the child in excessive quantity. . . .late at night. The pharmacy where the prescription had originally been filled was miles away and was closed." Lascoff[5] went on to state that the local pharmacist identified the tablets, notified the local physician of their contents, provided the antidote requested, and saved the life of the child. I believe that the only valid reason for identification by physical properties or the publication of tablet and capsule identification charts or guides is when such cases of poisoning occur; that is, a person cannot reach the physician who prescribed the medication or the pharmacy where the medication was dispensed. However, even though one life may be saved by identification by appearance, encouraging such a procedure may lead to other lives being lost.

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In 1953, Greenberg[9] stated that one of the results that students are expected to gain from compounding specialty prescriptions in college is familiarity with the physical appearance of the specialty drug and container.

In 1958, Katz[2] stated that state board identification procedures provide an opportunity to discover that candidates have never handled certain products which are very common in pharmacies today, and make the reliability of their internship questionable. Vitale[3] commented that the identification procedure "immediately pinpoints whether a particular intern is getting the proper preceptor training."

On the other hand, Swain[10] pointed out in 1938 that the Maryland Board of Pharmacy has come to the conclusion that it is a waste of time to give so-called specimens for examination. In addition, Fonda[11] reported in 1939 for the Standing Committee on Pharmacy by stating, "The committee feels that the identification of chemicals and galenicals upon the basis of superficial sensory examination is unscientific and detracts from the validity and reliability of the Practical Pharmacy Examination as a measure of the fitness of the candidiate to practice pharmacy. . . . In 1937, Dr. Albert Blakeslee presented 45 members of the American Philosophical Society with samples of sugar and asked that they identify this substance which they probably use every day. Of these eminent, trained scientists, only 2 of the 45 were successful in identifying it as sugar. It was reported as being tasteless by 11, bitter by 5, and sweet by 18 others, although they were not able to identify the sample." Other educators[12] pointed out in 1954 that it is not good policy to have students quizzed on their ability to identify proprietaries by sight, because color, shape, and odor are not basic properties and are quite often changed. These educators felt that it was a bad practice for the student to acquire a sense of false security.

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Dean Leuallen[13] stated in 1958 that many colleges give review courses in recognizing proprietaries and those who recognized the proprietaries (on board examinations) may simply have attended such a college. "Their (the candidates) practical experience may have been less valuable than those who could not recognize the proprietaries."

Perhaps you may differ with me; however, it is my opinion that identification procedures tend to give dangerous encouragement to reliance on identification by appearance instead of by the reading of the label, and the more the practice of identification by appearance is practiced, the greater is the danger.[14] Therefore, state board identification examinations should be eliminated because they tend to encourage the dangerous procedure of identification by appearance.

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* Footnotes omitted in original document in evidence.

PLAINTIFF'S EXHIBIT 138 — EXCERPTS FROM REPORT OF ATTORNEY GENERAL ABRAMS AND CONSUMER AFFAIRS COMMISSIONER RATNER ON NEW YORK GENERIC DRUG SUBSTITUTION LAW, MARCH 13, 1979

REPORT OF ATTORNEY GENERAL ROBERT ABRAMS AND CONSUMER AFFAIRS COMMISSIONER BRUCE RATNER ON NEW YORK GENERIC DRUG SUBSTITUTION LAW

Prepared
By

STEPHEN MINDELL
Assistant Attorney General
in Charge
Bureau of Consumer Frauds
and Protection

March 13, 1979

PURPOSE OF SURVEY

Between January 18 and February 14, 1979, a task force led by New York State Attorney General Robert Abrams' office and including New York City Consumer Affairs Commissioner

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Bruce Ratner's office and the New York State Board of Pharmacy,* conducted a field survey of randomly chosen retail drugstores to assess the extent of their compliance with the generic drug law.

The survey covered the five boroughs of New York City, Buffalo, the Capitol District, Syracuse, Rochester and the Counties of Nassau, Suffolk, Westchester and Rockland. In all, 283 drugstores were visited and presented with a prescription for drugs by an investigator posing as a consumer.

A prime objective of the field inspection was to uncover violations of the consumer protection laws including the Generic Drug Law (Education Law § 6810.6 and § 6816-a, Drug Poster Law (Education Law § 6826), Pharmacist Badge Identification Requirement (Education Law §6808-a), drug container and child safety cap requirements (USCA Title 15 Section 1471 et seq.) for purposes of approriate enforcement action.[1]

Another important purpose of the survey was to compile field data on how well the generic drug law and related consumer protection laws are working in order to determine the need for legislative changes and other action to strengthen the protection afforded to the public.

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* The Board of Pharmacy showed splendid cooperation throughout the survey — participating actively in the planning and execution of the survey and agreeing to launch disciplinary proceedings against pharmacies who violated the law. We extend sincere thanks to the Board and its Executive Secretary for this assistance. However, the results of the survey and other research have led us to certain criticisms of the performance and effectiveness of the Board and proposals for change with which the Board disagrees.

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SUMMARY OF FINDINGS

The Attorney General and the Commissioner found that a combination of factors is denying consumers millions of dollars in potential benefits from New York State's generic drug law. Because of resistance to change on the part of physicians, violation of law and other anti-consumer practices by pharmacists, and a lack of vigorous enforcement by the State Board of Pharmacy, it is estimated that less than one consumer in 25 reaps the full financial benefit of generic drug substitution.

Specifically, the survey disclosed that:

* 67 of the 283 pharmacies, nearly one quarter, violated the generic drug law when filling the prescription;

* even when they dispense a generic drug, pharmacists are not passing along the full dollar savings of those drugs to consumers;

* prices vary widely from pharmacy to pharmacy for both brand name and generic drug products. The retail price charged by some pharmacies for the generic substitute is often significantly higher than the retail price charged by other pharmacists for the brand;

* the State Pharmacy Board has given prosecution of violations of generic drug law and drug price poster law a low priority. Few proceedings (only 54) seeking a monetary penalty of a maximum of $500 have been brought. In 48% of these proceedings no penalty was imposed. In most others, the penalty imposed was $250 or less;

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* although violation of the generic law or the drug price poster law constitutes a class A misdemeanor, no cases have been referred by the Pharmacy Board to district attorneys for prosecution;

*the bulk of enforcement of these laws by the Pharmacy Board has come as a response to consumer agency interest and prodding and not as a result of the initiative of the Board;

* few New York prescriptions (22.5% are signed by doctors so as to permit substitution of less expensive generic drug products. Since the generic drug law became effective in April 1978, the percentage of prescriptions permitting substitution has declined;

* the present drug price poster is inadequate because it does not require a pharmacist to list his current selling price for both brands *and* generics in every instance and does not have clear cross references;

*the current notice to consumers at the bottom of the drug price poster provides little helpful information;

* a substantial number of pharmacists do not give prescription price information to consumers over the telephone thereby making comparison shopping difficult;

* the Pharmacy Board has not followed-up with doctors who are using prescription forms which do not comply with the generic drug law;

* composition of the Pharmacy Board is overly oriented toward the profession and has inadequate consumer

representation — only two out of eighteen members are public members;

* a concerted education program to alert prescribers and consumers to the benefits of the generic drug law is needed.

RECOMMENDATIONS

The names of the 67 pharmacies found violating the generic drug law and related statutes are before the Board of Pharmacy for the initiation of proceedings. The Attorney General recommended that vigorous action be taken, and he plans to monitor the proceedings closely. Notices of the opening of Board proceedings for the assessment of monetary penalties are being mailed this week.

In addition to this enforcement action, Attorney General Abrams and Commissioner Ratner recommend the following legislative proposals:

1. Criminal Enforcement: Education Law § 6811 should be amended to give the Attorney General statutory power to bring criminal prosecutions against violators of the generic drug law.

2. Civil Enforcement: Education Law § 6515 should be amended to give the Attorney General specific authority to seek restitution for aggrieved customers and a civil penalty for violation of the generic drug law.

3. Education Law § 6816-a should be amended to require pharmacists to pass along to consumers the full savings of generic drugs. The savings is to be measured by the

difference between the wholesale cost to the pharmacist of brand name and generic drugs.

4. Education Law § 6810.6a should be amended to eliminate preprinted signature lines "dispense as written" or "substitution permissible" and require prescriber to *handwrite* "medically necessary" if he disapproves substitution.

5. Education Law § 6810.6b should be amended to require prescriber to inform patient why substitution is not permissible.

6. Education Law § 6816-a should be amended to give consumers a limited override so that brand names can be dispensed instead of generics in emergency situations.

7. Education Law § 6826(3), the drug price poster law, should be amended to aid consumers in comparative shopping by providing both brand and generic prices for each drug listed and by rewriting the notice at the bottom of the poster.

8. Education Law § 6508 should be amended to require that 51% of the members of the Pharmacy Board and all other professional licensing boards be representative of consumer interests having no personal interest in the regulated profession.

9. The Federal drug formulary should be used to replace New York State's "green book."

Plaintiff's Exhibit 138

10. The Regents Rules should be amended to require a pharmacist to provide requested drug information over the telephone.

11. The Attorney General supports enactment of Senate Bill 1321 re: publication of a consumer generic drug guide by the State.

PLAINTIFF'S EXHIBIT 142 — STIPULATION DATED FEBRUARY 28, 1980 RE: RESULTS OF "CHUNG SHOPPING"

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Civil Action No. 78-372 (EHN)

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

STIPULATION

IT IS HEREBY STIPULATED AND AGREED by and between plaintiff and defendant, Premo Pharmaceutical Laboratories, Inc. (hereafter "Premo"), through their respective attorneys, that Mr. Douglas Chung of 344 East 17th Street, Brooklyn, New York 11226, a witness listed in the Pretrial Order herein, would have testified if called as a witness at trial as follows:

1. Mr. Chung is registered to practice pharmacy in the State of New York.

2. In or about December, 1979, at the request of attorneys for Premo, Mr. Chung conducted shoppings at twenty-five pharmacies in the New York metropolitan area. He shopped

Plaintiff's Exhibit 142

each twice, once with a prescription for CYCLOSPASMOL Dispense as Written, once with a prescription for Cyclandelate Dispense as Written.

3. In the twenty-five pharmacies shopped, there was no illegal substitution in connection with the prescriptions for CYCLOSPASMOL Dispense as Written.

4. In the twenty-five pharmacies shopped in connection with the prescription for Cyclandelate Dispense as Written, the prescriptions were filled in each instance with the generic product. Two of the prescriptions, however, were labelled Cyclospasmol generic and 14 of the 25 omitted the name of the manufacturer or of the manufacturer and distributor.

5. Two pharmacies which filled prescriptions for both CYCLOSPASMOL and Cyclandelate charged more for the generic than they charged for the CYCLOSPASMOL. Twenty-three of the pharmacies that filled prescriptions for both CYCLOSPASMOL and Cyclandelate charged less for the generic than they charged for CYCLOSPASMOL.

6. A chart showing the names of the pharmacies shopped, the price charged for equal quantities of the various products, and, in the case of the generic, the identification shown on the label, is attached hereto as Exhibit A.

Dated: New York, New York
February 28, 1980

Plaintiff's Exhibit 142

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Plaintiff's Exhibit 142

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Plaintiff's Exhibit 142

Name of Store	CYCLOSPASMOL PRESCRIPTION	CYCLANDELATE PRESCRIPTION
1. East View Apothecary 34 East 57th Street New York, N.Y. 10021	Ives Product $5.30	Cyclandelate $3.00
2. Four Corners Pharmacy 1749 Victory Blvd. Four Corners, Staten Island, N.Y.	Ives Product $5.75	Cyclandelate $3.95
3. Prescriptions Exclusive 1229 Third Avenue New York, N.Y. 10021	Ives Product $5.00	Cyclandelate $2.75
4. Prescription Limited of Madison Avenue 1151 Madison Avenue New York, N.Y. 11028	Ives Product $6.10	Cyclandelate $4.75
5. Rite Aid Pharmacy 146 East 36th Street New York, N.Y. 10023	Ives Product $3.92	Cyclandelate Bolar $2.30
6. Barney's Prescriptions 41 John Street New York, N.Y. 10038	Ives Product $3.95	Cyclandelate (capsules marked with #258) $1.99
7. Church Pharmacy 1300 Church Avenue Brooklyn, N.Y. 11225	Ives Product $4.98	Cyclandelate $2.98

Plaintiff's Exhibit 142

8.	Dan's Grand Avenue Pharmacy 42-16 30th Avenue Astoria, L.I.C., N.Y.	Ives Product $5.95	Cyclandelate Schein $3.45
9.	Group Drug Service 101 Maiden Lane New York, N.Y. 10038	Ives Product $4.50	Cyclandelate $4.75
10.	Sav-On Drug Stores 1545 Forest Avenue Staten Island, N.Y. 10302	Ives Product $4.28	Cyclandelate Vanguard $2.82
11.	D & R. Pharmacy, Inc. 146 Smith Street Brooklyn, N.Y. 11201	Ives Product $8.10	Cyclandelate $3.95
12.	Pathmark Pharmacy 376 Fulton Street Brooklyn, N.Y. 11202	Ives Product $4.09	Cyclandelate IDE Bolar $2.19
13.	DJ Drug 65-45 99th Street Forest Hills, N.Y. 11374	Ives Product $4.95	Cyclospasmol generic $2.45
14.	Willner Drug Shop, Inc. 1725 Foster Avenue Brooklyn, N.Y. 11230	Ives Product $4.95	Cyclandelate $3.25
15.	Norwood Rexall Drugs 31-12 Broadway Long Island City, N.Y.	Ives Product $4.95	Cyclandelate Ace Inwood $3.95

Plaintiff's Exhibit 142

16.	Group Drug Service 3 Beekman Street New York, N.Y. 10038	Ives Product $4.50	Cyclospasmol generic $3.95
17.	Health-Wise Pharmacy 2017 Church Avenue Brooklyn, N.Y. 11226	Ives Product $5.10	Cyclandelate $8.35
18.	Lipton Chemists, Inc. 14 Newkirk Plaza Brooklyn, N.Y.	Ives Product $4.95	Cyclandelate $3.25
19.	Abraham & Strauss Prescription Dept. Fulton at Hoyt Brooklyn, N.Y.	Ives Product $4.64	Cyclandelate Inwood $1.99
20.	Bonus Drug, Inc. 31-04 Broadway Astoria, N.Y. 11106	Ives Product $4.75	Cyclandelate Premo $3.84
21.	Kings Pharmacy 93-17 63rd Drive Rego Park, N.Y. 11374	Ives Product $4.79	Cyclandelate generic $2.99
22.	Pathmark Pharmacy 880 Third Avenue New York, N.Y. 10022	Ives Product $4.19	Cyclandelate $2.29
23.	Greenfield the Chemist 1525 Cortelyou Road Brooklyn, N.Y.	Ives Product $5.25	Cyclandelate pharmadyne $2.75

Plaintiff's Exhibit 142

24.	BJS Drugs Inc. 69-65 Yellowstone Blvd. Forest Hills, N.Y. 11375	Ives Product $4.53	Cyclandelate $2.49
25.	Prescriptions Limited 7 John Street New York, N.Y.	Ives Product $3.75	Cyclandelate Cord $3.25

PLAINTIFF'S EXHIBIT 143 — JOINT DESIGNATED EXCERPTS OF DEPOSITION TESTIMONY OF PREMO BY SEYMOUR BLACKMAN, MAY 4, 1978

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

Civil No. 78-C-372

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

Deposition of Defendant Premo Pharmaceutical Laboratories, Inc. by SEYMOUR NORMAN BLACKMAN taken by plaintiff on Thursday, May 4, 1978.

* * *

[4] SEYMOUR NORMAN BLACKMAN having been first duly sworn by the Notary Public was examined and testified as follows:

EXAMINATION BY MS. DRISCOLL:

Q. Would you state your residence address for the record Mr. Blackman? A. 284 East Palisade Avenue, Englewood, New Jersey.

Plaintiff's Exhibit 143

Q. And are you employed? A. I am.

Q. By whom? A. By Premo Pharmaceutical Laboratories, Inc.

Q. And is that one of the defendants in this case? A. Yes.

Q. And what is your position at Premo? A. President and chairman of the board.

Q. What is your educational background, Mr. Blackman? A. Bachelor of Science, Columbia University College of Pharmacy, and two years of medical school.

Q. And did you get a degree? A. Not at medical school, but in pharmacy.

Q. Yes, and when was that? A. 1942.

[5] Q. And can you describe for us generally what your work experience has been since graduation? A. After graduation I did go to medical school for two years, and in 1944 I was in the U.S. Navy as a Pharmacist's Mate, and finished there in 1946.

I went to work at that time for Premo Pharmaceutical Laboratories until 1951. I left and formed my own company, Omega Hospital Supply, Inc., stayed there until 1959 when I made arrangements to work for Premo again for two years, and I split my time during 1959 and 1960.

At the end of 1960 I returned to Omega. I remained there till 1972, when I acquired Premo Pharmaceutical Laboratories and became the president.

Plaintiff's Exhibit 143

* * *

Q. Would you tell us generally what business Premo is in? [6] A. They are manufacturers of generic drug products.

Q. And how long have they been in business? A. As a corporation since 1927. Prior to that, I think in 1916, it was Blackman and Fink, and then in 1918 it was Blackman and Blackman, but the corporation as Premo was formed in 1927.

* * *

[7] Q. And how many people are on your sales staff? A. Three.

Q. And what do they do? A. Three people. They contact wholesale druggists and offer our products for sale, mostly by telephone.

* * *

[10] Q. And to whom was that catalog distributed? A. It was mailed to every known drug wholesaler and chain and cooperative buying organization in the United States. Some three thousand in all, I believe.

* * *

[12] A. I think our employees make little or no effort to sell this product.

* * *

Plaintiff's Exhibit 143

Q. What is the basis for your conclusion that they make little or no effort to sell Cyclandelate? A. It is not a very profitable item. We instruct them not to push it. It is manufactured by many other generic houses. It is quite competitive and we have better items to sell that have a higher volume in the trade and are more profitable.

* * *

[13] Q. Now, did you play any role in the decision of Premo to begin selling Cyclandelate? A. Yes.

Q. And would you please tell us what your role was? A. Well, I remember that we were looking for products to put into the line. We were discontinuing many products. Our sales manager at the time said, "Here is a product where the patent has expired; it enjoys a fair sale; other generic houses have it. Why can't we have it?" And —

* * *

[14] Q. Did you play any role in selecting the particular form in which Premo's Cyclandelate product was sold, and by "form" I mean the color, shape, whether it is a tablet or a capsule. A. Yes.

Q. And did you make that decision? A. Well, I was part of the decision-making process.

Q. And who else was? [15] A. Well, there was myself and my son John and Mr. Silverang.

Plaintiff's Exhibit 143

Q. And can you tell me why it was decided to sell Premo Cyclandelate in the particular form as previously defined in which it is sold?

MR. COBRIN: Could I hear the previous definition of the form, please?

THE WITNESS: Color, shape, size. (A portion of the record was read back by the reporter.)

MR. COBRIN: And could you read the pending question, please?

(The pending question was read back by the reporter.)

THE WITNESS: Yes, because its form indicates the medicinal ingredient and the dosage strength.

Q. What do you mean it indicates the medicinal ingredient; can you explain that? A. In the medical field the form, which is the color, shape, size, or tablet or capsule, as you stated, would identify the active medical ingredient and the strength of the active medical ingredient.

Q. Do you know of any other blue capsule on [16] the market other than one which has the generic name Cyclandelate? In other words, are there any other blue capsules? A. Yes, I have seen other blue capsules.

Q. Do those blue capsules identify an active ingredient? A. Yes, I would say so.

Q. It would be a different active ingredient, though, wouldn't it? A. It might. It could be the same. If it is the same

Plaintiff's Exhibit 143

color blue or the same color blue and red it would be Cyclandelate. I know of no exception.

Q. Now — A. —but this color of blue and gray would be anything but Cyclandelate.

Q. In other words, you have never seen or don't know of another capsule other than Cyclandelate which is in the particular shade of blue?

* * *

A. Well, I know of none offhand, but I think the blue is a standard blue color and there may be some.

* * *

[21] Q. Now, if I showed you your Exhibit 3 and you did not know what bottle it came from, could you tell me whether this capsule, Exhibit 3, is a Premo product or not? A. No, I could not, but I could readily differentiate it from Ives' product.

* * *

[22] Q. And if you were shown just this capsule and did not know what bottle it came from, could you tell it was a Premo product? [23] A. I could not.

* * *

Q. At the time that the selection of the color blue and the selection of the colors blue and red was made, were you aware of the Ives Cyclospasmol product and its coloring? A. Yes.

Plaintiff's Exhibit 143

Q. Did you copy that coloring? A. Yes.

Q. Now, you stated at the beginning of your testimony that your company is in the business of selling generic drugs and can you just, so that we are clear about what you mean, define what a generic drug is for the record? [24] A. Well, it has a very broad definition, but my definition is simply a pharmaceutical product at a reasonable price.

Q. That is your definition of a generic drug? A. That is my definition.

* * *

Q. Have you ever used a brand name to identify your Cyclandelate capsules? A. No.

Q. Is that true of your other generic drugs as well? A. No.

Q. In other words, sometimes you do use a brand name? A. Yes.

* * *

[26] Q. And is your Isoxsuprine product in the same color, dosage, form and size as the Vasodilan product? A. Precisely.

Q. Was that intentional? A. Of course.

Q. Why do you say "of course"? A. Because it is standard operating procedure for fifty years. And no one wants to cause confusion in the medical business. Very dangerous.

Plaintiff's Exhibit 143

Q. It is standard operating procedure of Premo for fifty years? A. I would say of Premo surely, and perhaps other people who are in the generic drug business who bring medication out in a second position — in time, I mean.

Q. Now, you spoke about confusion.

[27] Can you tell me why you believe that the color must be duplicated to avoid confusion?

MR. COBRIN: Are we limiting ourselves to Cyclandelate?

MS. DRISCOLL: Yes. A. Color, shape, size, dosage, form in a tablet, capsule, liquid, odor, taste are all things that can be perceived by people by their sensations. And starting with the patient, the patient identifies his medicines by all of these things, because traditionally the medication was never labeled, and —

Q. Pardon me? A. — even — the medication was traditionally never labeled with the active ingredient. And this has been so for hundreds of years.

And starting with the patient, they relied on the color, shape, size, odor to know whether they were getting the right chemical entity and the right dosage of that chemical entity.

The same thing prevails down the line, so the nurse would likewise identify the medication by all these physical traits, and so would the physician.

And so would staff in the hospital. And so would assistants in the pharmacies.

Plaintiff's Exhibit 143

* * *

[30] A. I never made that statement. I never indicated that any nurse would simply grab a blue capsule because she knew Cyclandelate 200 mg. was a blue capsule. Quite the reverse.

If she saw a red capsule, she would be alarmed and know that a mistake had been made. But no, she would not go over and simply grab a blue capsule because it was blue.

I never indicated that. I think it's idiotic.

* * *

[31] Q. Now, are you aware of any generic products on the market that do not copy the nationally branded generic?

* * *

A. I know of a recent effort to products manufactured by major drug manufacturers masquerading as generics that are marketed in different color. I don't know what they are trying to prove. It's a very recent movement.

* * *

[32] To come back and answer the question more specifically, I know of no generic drug that does not come in the same color, shape, size as a name brand drug.

* * *

[33] Q. Are all phenobarbital tablets in the same color, size, shape? A. No.

Plaintiff's Exhibit 143

* * *

[37] A. No, we do not advertise it. We think it's a stiff product.

Q. What does "stiff" mean? A. Very poor sales potential.

* * *

[44] Q. Now, below the word "Cyclandelate capsules" there is a parentheses and the word "comp." appears there. What is that an abbreviation for? A. Comparable.

Q. And what was the basis for your stating that in parentheses "The product is comparable to Cyclospasmol"? A. Well, Cyclospasmol contains 200 mg. of Cyclandelate and it has the same active ingredient.

* * *

Q. Now, for example, I will show you [45] Blackman Exhibit 1, where there is a reference to Cyclandelate capsules and the words "Cyclospasmol equivalent."

What does "equivalent" mean in that connection? A. It means it has the same physiological activity, the same uses, indications, cautions, dosage.

* * *

[47] Q. Now referring for example to Exhibit 10 and to the heading over the top column "Premo Brand," are the items listed below that heading Premo brands? A. Oh, yes, they are all. We offer all those items under the Premo brand.

Plaintiff's Exhibit 143

Q. And what about those in the right-hand column, are they Premo brands? A. They are brands other than Premo.

Q. And can you tell me how in your opinion a [48] wholesaler was to know that they were not Premo brands, if you can give me an opinion on that. A. Yes, I can give you an opinion. The wholesalers that we sell to are known as generic specialists and it is simpler to list the generic product and the equivalent product alongside it so that they could identify which product it was equivalent to or which name brand it was equivalent to.

So it's just a form, and even though it doesn't say "brands other than Premo" at the top of the right column, the customer is very well aware of what it is.

Q. Now I refer to Exhibit 11. Is this one of those that was mailed out or is this an internal one? I didn't keep track — A. I believe this was mailed but not to a large group, about 200.

Q. And this has no heading except for "tablets and capsules." Can you tell me what is in the left-hand and what is in the right-hand column there? A. Yes, this is a mailing to a select group of customers, about 200 wholesalers who specialize in generic drug products, and they are used to seeing the generic product in the left-hand column and the [49] name brand column, a list of — on the right-hand side.

So that while there is no indication as to what is listed here, the customer knows very well that the left-hand column is the Premo generic and the right column the name brand equivalent.

Plaintiff's Exhibit 143

Q. Now when you say it's a custom, is it a custom of Premo or a custom of generic drug houses generally? A. Surely a custom of Premo and generally a custom of generic drug houses.

Q. Now when did you first start your custom of listing Premo products on the left and branded products on the right? A. I guess about 1971.

Q. And in what media was this used? What I mean is do you do this in product lists, price lists, catalogs? A. In a quick mailing of product lists we would use this format. In formal catalogs we would not. Formal catalogs showing prices and uses perhaps and indications, we would not use columns but we might state the Premo name and in parentheses "equivalent to a certain name brand" and not use columns at all.

Q. Now I notice in Exhibit 8 for example [50] that contrary to custom you have the branded one in the left-hand column and the Premo product in the right-hand column.

Can you tell me if this is also a custom of Premo? A. No, it is not a custom of Premo. This happens to be a price sheet and the columns are plainly identified, those on the left national brand and in the right column the heading says "Premo equivalent." And it is not a custom but I don't think there is any confusion here and I am not ashamed of it.

Q. Now referring to Exhibits 9, 10, 11, 12, 13 and 14, which are exhibits with the columns, can you tell us how the custom would become known to people where even on these particular product sheets there never was any heading for the right-hand column; in other words, how would people get to know that that's what this means if there never was a heading there? A. Well, people are generally intelligent and animals of

Plaintiff's Exhibit 143

habit. You don't have to identify both columns, they know we are a generic house, if the left column says Premo brand and the right column is unidentified the human being, with his infinite wisdom would know the right hand column was the name [51] brand.

* * *

[67] Q. Have you ever used your NDC number by affixing it directly to a Cyclandelate capsule? A. Not to my knowledge.

* * *

[68] Q. Have you filed a new drug application in connection with Cyclandelate? A. We have attempted to file, but I believe the answer to your question is no. We have not filed.

Q. Have you filed an abbreviated new drug application in connection with Cyclandelate? A. I misunderstood your first question. We have never attempted to file or filed a new drug application. We attempted to file an abbreviated new drug application, but we have neither one on file, an ANDA or an NDA.

Q. Can you please state for the record why your attempt was apparently foiled? A. Dr. Seif's office, who handles abbreviated new [69] drug applications, stated that since the drug has never been shown to be effective, it could only be marketed as other Chapter XIV drugs, or what we call in the trade Judge Brieant decision drugs, without an ANDA.

The original manufacturer, however, which had an NDA on file would be able to continue to sell the product under their

Plaintiff's Exhibit 143

original NDA, notwithstanding the law on the books that requires a drug to be both effective and safe.

It is a peculiar twist, a judicial decision over a law, and we suffer in that we are not allowed to apply for an abbreviated new drug application.

* * *

Q. Now, you said "Dr. Seif's office". Was it Dr. Seif himself who communicated this to you or was it someone else in the office? A. It was Dr. Seif specifically.

Q. And did he talk to you personally? A. He did.

Q. When was this? [70] A. In his office.

Q. When? A. I can't give you the specific date.

Q. Can you give me the year? A. No, I would be guessing. I could, of course, look it up in the records.

Q. Would you please? A. Yes.

Q. We will leave a space and insert the date of the meeting.

(Information to be furnished by the witness as follows:)

Q. What did Dr. Seif say to you and what did you say to him in connection with this matter of your attempt to file an ANDA? A. He said he would give me a number, a filing number, but not to consider the application as officially filed because his legal department advised him not to accept the abbreviated new drug application.

Plaintiff's Exhibit 143

Q. And did — excuse me. A. He further said that according to Judge Brieant's [71] decision, we could continue to sell this drug without an effective new drug application until the holder of the NDA showed the product to be effective, and once the holder of the NDA proved the product to be effective, they would accept our application.

* * *

[88] Q. Have you ever done any clinical testing on Cyclandelate, the Cyclandelate product? A. No.

* * *

[89] Q. And do you know whether the Cyclandelate product is a — can we call it a one-time product, or one that is taken regularly over long periods of time? A. If the physician thinks it works, it would be used over a protracted period of time, perhaps for the remainder of the natural life span of the individual taking the product.

* * *

[97] Q. Now, is it your impression that the plaintiff in this case is trying to prevent your sale of Cyclandelate?

* * *

[98] A. It is my distinct impression that the Ives company would like to foreclose or forestall me from making any sales of Cyclandelate by whatever means they could find.

Q. And that is what your answer is based on? That understanding is the basis for your answer about your good name and credibility, and so forth — A. No, not at all.

Plaintiff's Exhibit 143

Q. — being hurt? A. It has nothing to do with my answer. My answer to a question is predicated on the question, not on an attitude that I may have to a certain company.

Q. Would your good name, believability, credibility and your ability to instill confidence in people [99] be injured if you were allowed to sell Cyclandelate but in a color other than blue or blue and red? A. I believe so.

Q. And what is the basis of that belief? A. I believe I have instilled in my customers, throughout the many years that I have been in this business, that it is my right and my privilege to supply medication in a safe form that will not injure the patient or cause confusion in the medical field. And this has to do with my good name and my professional status.

Q. What do you mean by "safe form"? A. If you put medication out in a color other than what we are — the product would indicate, or the dose would indicate, you might cause irreparable damage.

Q. How? A. Well, let's say — let's say, for example, what Ives would seek here came about and every manufacturer put out the same product in a different shape, size and color. The confusion would be legion. There would be no way that a nurse or — or an aide administering medication in a hospital could know what it was they were dispensing by looking at it; nor could a patient receiving medication in the pharmacy know what they were getting, because traditionally patients were kept in [100] the dark. Not only didn't they know the manufacturer, which is so obscure as to be almost ludicrous, but they didn't even know the name of the medication they were taking, and they relied very much on the color, shape and size of the product.

Plaintiff's Exhibit 143

If this were taken away from the patient, their whole safety mechanism would be destroyed.

Q. So that — A. And that would be dangerous.

Q. What is the "safety mechanism"? I really want — I am not sure what you mean.

* * *

Q. And I am saying I don't know what the words "safety mechanism" mean. A. I am referring to the sensibility of touch, sight, [101] smell, which protects human beings from danger. When we see something that is red, we react. When we see medication that we are taking, that is presumably active in order to do something to us, in a color that's different, or in a shape that's different, or in a size that's different, if this is denied us as human beings, the safety mechanism of our perception and our sensibilities would be denied to us, and that, madam, is dangerous.

Q. Yet you testified, did you not, that phenobarbital is sold in several different shapes? A. I did not testify to that, but I merely answered yes or no to a question, and I was not allowed to testify. But I could testify that phenobarbital is principally a white bisected tablet, different strengths coming in different sizes.

There are a few — I would call them exotic products in the market, of color which is precisely there to masquerade and deny the patient the knowledge of what they are taking. And so some manufacturers — not I — put their product out in a false guise to deny the patient the right to know what they are using. And that is what you are referring to now.

Plaintiff's Exhibit 143

* * *

[105] Q. Mr. Blackman, do you sell your Cyclandelate product with the purpose of giving the pharmacist a product which it can sell instead of Cyclospasmol? And I don't mean to imply illegally. I just mean are you doing this to offer him a product that he can sell instead of the advertised product? A. Yes.

* * *

Q. Now, I am going to show you what has been submitted as Lowenkron Exhibit L-X and state on the record that this is a photograph of Cyclandelate capsules —

MR. COBRIN: Do you have —

Q. — the label of which refers to Forest Laboratories and ask if you will look at Exhibit L-X.

MS. DRISCOLL: I am sorry, do I have what —

MR. COBRIN: Do you have the actual — strike it. A. Is there a question for me?

Q. No, I am just asking you to look at it. [106] A. I have looked at it. Thank you.

Q. Now it appears from this photograph that Cyclandelate 200 mg. capsules are yellow and the 400 mg. are green; would you agree with that just judging from the photograph? A. Yes.

Q. In your opinion are they unsafe drugs? A. Yes.

Plaintiff's Exhibit 143

* * *

Q. Now the 200 mg. Cyclandelate capsule in that photograph is the color red. Do you consider that to be an unsafe product? A. Unsafe and ill conceived.

Q. Pardon me? A. Unsafe and not well conceived.

Q. Is there a reason why your answer was elaborated in connection with the red capsule as [107] opposed to the yellow and green ones, namely ill conceived? A. I think they are all ill conceived — not well conceived, and I think that any practice that leads to proliferation of shapes, colors and sizes for a medication that's well known is dangerous and badly conceived and works not in the well interest — good interest of the public.

* * *

[111]A. The prescription label in most states requires the name of the manufacturer. If it's a trade name they do not have to put the name of the manufacturer.

So if it were Cyclospasmol it would say on the label "Cyclospasmol." If it were Cyclandelate of a generic type, the label would say "Cyclandelate Premo."

Now let's say I was in a state that did not require the identity of the manufacturer on the label — and there are such states; the next thing I would go to is to see if there were an imprint on the capsule.

Ives' capsule is imprinted with the name and therefore would be readily identifiable.

Plaintiff's Exhibit 143

* * *

[115] Q. Do they ever in their orders refer to the color of the product? A. I have no direct recall of their ordering the product by color. So I would say no.

* * *

[117] Q. Now, is your use in connection with the Cyclandelate products of the same color, shape and appearance as the Cyclospasmol products have — is that an essential part of your promotion of your product?

* * *

A. In every respect but their imprint of their name.

Q. Is the fact that your product has the same color, shape and appearance important to your promotion of your product? A. It is important, yes, in the promotion of the [118] product.

* * *

Q. Have you ever sold your Cyclandelate product to any governmental entity? A. Not directly. Not to my knowledge.

Q. Have you ever attempted to bid for government sales in connection with your Cyclandelate product? A. Not to my knowledge.

* * *

Plaintiff's Exhibit 143

[122] Q. Now, referring to Exhibit 9: Was there a reason why the color of Cyclandelate from Premo was not mentioned, whereas the color of at least three other products was?

* * *

A. The product Hydrochlorothiazide, the patent was [123] owned by Ciba with an exclusive license through Merck Sharpe & Dohme. They marketed their color — their product was a peach color — I mean a yellow color — and Merck Sharpe & Dohme was a peach color. And so, in that case, there were two manufacturers of a patented product distributing the product into the marketplace, and Ciba with the name Esidrix and Merck Sharpe and Dohme with the name Hydrodiuril. The products were the same size, and they were tablets, but there was a slight difference in color, one peach and one yellow.

And, so, generic manufacturers made both colors available. And there was a little confusion in the trade. It's an exceptional thing to have two different acceptable colors of the same medication, as stated, but all the generic manufacturers leaned toward the Merck product because they perhaps sold 75 percent of the name brand Hydrodiuril — Hydrochlorothiazide.

We no longer make either peach or yellow, but we did, after a while, discontinue the Esidrix-type color.

The same thing applies, the identical thing, to the liquid preparation potassium chloride. There were two leading manufacturers. Both came out about the same time. One was red, Kay Ciel, and the [124] other was yellow, Kaochlor. And so both colors were made available.

* * *

Plaintiff's Exhibit 143

[125] Have you ever had occasion to sell a tablet or capsule in two colors in any other instance?

And here, again, by "two colors," I do not mean two colors joined into one capsule, I mean you sold the same product in, for example, red and purple. A. Yes.

Q. And what was that occasion? A. The occasion was when we sold APC tablets to physicians who wanted to dispense aspirin compound and have it look like something else, and they wanted to keep the truth from their patients that they were simply taking APC tablets, so they were made available in not only white, which was standard, but in red and green, to mislead the public.

Q. And you did the same? You complied with this request? A. Yes. Hospitals and physicians found that this was a way to make medication more effective. Patients knowing that the aspirin compound didn't work, when they got something in red or green, they thought it was stronger and they thought it was working better.

* * *

[128] Q. Do you know if there are wholesalers who prefer getting a branded product as opposed to a generic product? A. I know of no wholesaler that would prefer one over the other. They have sales for both and they require both.

Q. And what about pharmacies? A. Yes, there are pharmacists who prefer to deal in name brands only.

* * *

Plaintiff's Exhibit 143

Q. And can you answer as to physicians; are there physicians who prefer to prescribe brand name products? A. Yes.

* * *

[129] Q. Are there physicians who prefer to your knowledge to prescribe for example Cyclospasmol as opposed to a generic Cyclandelate? A. There are.

Q. And are there patients who prefer to have brand name Cyclandelate, namely Cyclospasmol, prescribe for them as opposed to a generic? A. I — I am — I know there are —

* * *

[133] Q. And do you have knowledge based on this experience of yours as to — or do you have an opinion, excuse me — as to whether or not it is easier for a pharmacist who wishes to illegally substitute — I am not saying that you have any specific knowledge of that, but do you have an opinion as to whether it is easier for such a pharmacist to fill a Cyclospasmol [134] prescription with Cyclandelate capsules if the Cyclandelate capsules are the identical color —

MR. COBRIN: I'd like to hear the question.

Q. — as to the Cyclospasmol?

* * *

[135] THE WITNESS: Yes, I think I can. A. I think it's obvious if a man is going to do something illegal like pass

Plaintiff's Exhibit 143

counterfeit money it's easier if he has a good imitation. And to that extent if a man is intent on breaking the law the same color, shape, size, and so forth would make it easier for him to break the law.

* * *

[136] Q. No, I believe you have also testified, Mr. Blackman, that you are somewhat familiar with the way drugs are used in a hospital atmosphere.

Could you describe this form us in more [137] detail? Is there a room where drugs are kept generally? A. Generally, there is a pharmacy in the hospital and orders are sent down to the pharmacy and they will for most medications send up a unit dose for the medication — for the patient.

In some cases they send up a day's supply. Let's say, for example, a patient is to take three capsules a day. Three capsules would be sent up for the patient. The name of the medication would be indicated, the name of the patient and the bed number, and the nurse in charge of dispensing medication would take one of, say, three capsules and at a prescribed period bring a tray around from bed to bed, giving each patient a paper cup or a plastic cup containing the medication.

Q. And there would be an indication of which medication was for which patient, so that there would be — A. Yes, to start out that exists, but when the medication leaves the nurse's desk it is put on a tray and there is an indication as to the bed and the patient's name, but there is no longer an indication as to what the medication is, and if it were of a different [138] color, shape or size, or if all manufacturers used their own color or

Plaintiff's Exhibit 143

their own dosage form, some being a pill, some being a capsule, an awful lot of confusion and — could result, and there surely would be danger.

Q. Now, would a nurse, if she saw, for example, a color that she was not familiar with — would it be her professional responsibility to check with the doctor in charge? A. Yes; with the pharmacist first. He —

Q. With the pharmacist first? A. Yes, it would be her professional responsibility I think if she didn't check she might be liable for a court suit.

* * *

PLAINTIFF'S EXHIBIT 144 — JOINT DESIGNATED EXCERPTS OF DEPOSITION TESTIMONY OF INWOOD BY SEYMOUR FIELD, MAY 19, 1978

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

Deposition of Inwood Laboratories, Inc., by SEYMOUR FIELD, taken by plaintiff . . . on Friday, May 19, 1978,

* * *

[4] SEYMOUR FIELD, having been first duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION BY MS. DRISCOLL:

Q. Would you state your residence address for the record, Mr. Field? A. 153-11 58th Avenue, Flushing, New York 11355.

Q. Are you employed? A. Yes.

Q. By whom are you employed? A. Inwood Laboratories.

Plaintiff's Exhibit 144

Q. What is your position at Inwood Laboratories? A. Vice president in charge of sales and marketing.

Q. How long have you been with Inwood? A. A little over five years.

* * *

[9] Q. To what kind of customers does Inwood sell, in other words, what categories of customers? A. Wholesalers, distributors, chain stores, some hospitals.

Q. In what manner does Inwood promote its product, or promote the sale of its product to these customers? [10] A. We have two or three agents throughout the country who call on some of these accounts, mostly by telephone, since they cover large areas of the country, also by flyers that we mail out which were given to you, and basically that's the way we contact people.

* * *

[16] Q. Is it one of your large sellers? A. It would be in the upper ten.

Q. What was that? A. The upper ten of the items that we make. But whether it would be the largest or the next largest, it would be difficult for me to answer at this point.

Q. Is it an important part of your business, do you believe? A. Not really.

* * *

Plaintiff's Exhibit 144

[17] Q. In what other sizes, if any, are the cyclandelate capsules sold by you? A. Five hundred, thousands.

* * *

[18] Q. Is that an Inwood products? A. Yes.

Q. How do you know that? A. Because you took it out of a bottle that was so marked and sealed.

Q. Is that the only way that you know?

Can you tell by looking at it independently? A. No.

* * *

[19] Q. If I just showed you this red-and-blue capsule and you didn't know what bottle I had taken it from, would you know whether it was an Inwood product or someone else's products?

* * *

[20] A. I would not.

Q. Do you know when Inwood began to sell cyclandelate? A. To the best of my knowledge, in April of 1976.

Q. In April of 1976, did it sell it in both the 200 milligram and the 400 milligram forms? A. Two hundred miligram [sic] first; shortly thereafter 400 milligram.

Plaintiff's Exhibit 144

Q. When you say "shortly thereafter", would it have been — A. A few months.

Q. — a few months? A. Yes.

* * *

[21] Q. Can you give us the reasons why you selected blue for the 200 milligram capsule? A. The company had received many requests from generic distributors throughout the United States requesting the product in the size, shape and color.

* * *

[22] Q. What about the 400 milligram? What were the reasons for slecting the red-and-blue color for the 400 milligram capsule? A. Generic equivalents are generally the same size color and shape, in order not to confuse the entire medical field.

Q. The same size, color and shape as what, sir? A. As any other product which you produce generic.

* * *

[25] A. Naturally all products that are released to the trade are properly assayed as to chemical structure and impurities, dosage release, and whatever, whatever other criteria is required to produce a prescription item.

* * *

[26] Q. Do you know of any other generic cyclandelates currently on the market? A. Yes. They are produced by several

other generic manufacturers, such as Chelsea Drug, Cord Laboratories, Premo Pharmaceutical, Bolar, MD.

* * *

[28] Q. Do you know of any generic cyclandlelate [sic] or cyclandleate [sic] at all presently being sold that is not blue in the 200 milligram dosage size? A. Yes. Forest Laboratories, the parent company of Inwood Laboratories.

* * *

A. As cyclandelate 200 milligram, lime green color.

* * *

[29] Q. Do you know when Forest began distributing that form of cyclandelate? A. Approximately a year ago.

Q. Is it still distributing it? A. We are not.

* * *

[30] Q. Would you just tell us for the record what Exhibit 11 is, sir? A. Cyclanfor capsules, 400 milligram.

Q. Is that a Forest product? A. That is correct.

Q. When was that first distributed, if you know. A. Also approximately a year ago.

Q. Is that still being distributed? A. No.

Plaintiff's Exhibit 144

Q. To what kinds of customers were 10 and 11 di
if you know? A. Hospital accounts. Hospitals.

* * *

[32] Q. Are there any instances in which Inwoo
generic drug products has used a color different from
of the national brand product? A. Not to my know

Q. Has there ever been an occasion when Inwoo
a generic product in one color and then, for some re
had to change that color subsequently? A. No
knowledge.

* * *

[36] Q. Is it your practice for your various generic
to ever put your NDC number on the capsule? A.
time we do put an NDC number on a capsule is wh
control substance, which is required by law. Otherwise
not done it in the past.

* * *

[37] Q. Did there come a time, Mr. Field, whe
filed with the Food and Drug Administration for eit
drug application or an abbreviated ne
application? A. We did file.

* * *

[40] Q. Have you ever discussed with representati
Food and Drug Administration your ne
application? A. I didn't personally, but our cons

regulatory affairs, Mr. Joseph Barrows, had contacted Dr. Marvin Seife, who is in charge of this and was told that under paragraph 14 of Judge Bryant's decision, that they could not give ANDA.

* * *

[44] MS. DRISCOLL: "Plaintiff Ives is the holder on the original patent on this drug."

Q. I want to know just the basis of that statement which you made under oath. A. I can answer it in this fashion. We never manufacture a product until the product is off patent. When we are sure of this, we then proceed to manufacture the product.

* * *

[46] Q. I believe you state in this affidavit that Cyclospasmol is more expensive than the Inwood cyclandelate, is that correct?

* * *

[47] A. That is correct.

Q. At which level of distribution is it more expensive?

For example, at the initial sale, is your cyclandelate less expensive than Cyclospasmol; at the manufacturer's level, when you are selling to a wholesaler? Do you know? A. Our product is less expensive at all levels of sales.

* * *

Plaintiff's Exhibit 144

[48] Q. Have you ever done any actual study of the market for cyclandelate by, for example, going to pharmacies and finding out, in fact, whether or not the generic cyclandelate is sold to the ultimate consumer at a price less than Cyclospasmol? A. I didn't.

* * *

[49] Are you aware of any unlawful substitution other than in this case? A. I am not personally aware of this situation.

* * *

[52] Q. Is it your practice in the mailings that you distribute to prospective customers to indicate the color of, for example, the cyclandelate that you are offering? A. We do this on all submissions of price lists with or without prices.

Q. Why is that? A. To acquaint the prospective buyer that he is getting a generic equivalent, meaning the same product, the same size, shape and color, which is what, as I stated [53] earlier, is required by many states today under the substitution generic laws.

Q. You have been in the drug industry almost forty years, correct? A. Yes. All my life.

Q. Have you been aware that there are pharmacies who do make illegal substitutions in connection with generic products? A. I would say that I am aware of it, but —

Q. It could happen? A. It could happen. I am sure that many of them are prosecuted because there are laws on the statute covering the substitution.

Plaintiff's Exhibit 144

Q. In your opinion, as someone who has been in the drug industry for forty years, does the fact that a generic product is the identical color as a national brand product that might be prescribed by a physician, does the identity of color facilitate the ease with which a pharmacist could illegally substitute?

* * *

[57] Q. I gather, Mr. Field, that it is the position of Inwood that if you are enjoined from selling cyclandelate in blue and blue-red capsules, that you will be injured, is that correct? [58] A. Not really. It is a very small part of our business. It is also not one of the most profitable markets that we market today. I would say that we would not — we might be slightly affected, but not injured.

* * *

[60] Q. Does Inwood sell what it considers the generic equivalent of Papaverine? A. We do. It is not listed on this for the simple reason that the material is very difficult to obtain.

Q. What color is Papaverine — is it a capsule? A. It is a capsule.

Q. What color is it? [61] A. The shell of the capsule is brown and clear and the pellets or the seeds which are — they are white.

Q. Do you know of any other companies that sell — I guess the generic name is papaverine hydrochloride? A. That is the generic and the chemical name of the product.

Plaintiff's Exhibit 144

Q. Do you know of any others, other than Inwood, that offer papaverine hydrochloride capsules? A. There are others.

Q. Do you know what colors the other manufacturers use? A. The same colors.

Q. The same as Inwood's? A. With one, maybe, exception.

Q. What is the exception? A. I believe that U.S. Vitamin had or has.

Q. That is the only one that you know of? A. Yes.

Q. Do you know whether the U.S. Vitamin papaverine hydrochloride is the same dosage form as — A. The dosage is the same. However, they claim a different process which they call a microdialysis [62] process for producing the seeds for the long acting effect of the drug. That is the reason that they do that, to differeniate between the national brand product and their product.

[66] Q. Would the same statement be true, namely that the colors play no role if the purchaser that you were talking about was one of the intermediary purchasers, such as a pharmacist, for example? Does the color make a difference to the pharmacist? A. It certainly would.

Q. Why is that? A. Because of his past experience in handling drugs and expecting the generic color, which is widely used today, in all phases of pharmacy. If we were to institute a different color and put it into any city hospital, the confusion would be of a chaotic nature.

Plaintiff's Exhibit 144

Q. In a city hospital? A. I am saying where a lot of professional people would be handling products, generically, the generic equivalents to the brand name, there would be no end to the confusion and great apprehension on the patient's part who has taken, been using a different color.

[67] Q. What is the basis for this statement that you just made, what is the personal knowledge that you have of that conclusion? A. My vast experience in selling directly to hospitals, nursing homes, purchasing agents, throughout the United States.

Q. Have you ever discussed with them what a specific change in color would do? A. Absolutely.

Q. Have you ever discussed the cyclandelate color with any of these people?

* * *

A. We did receive objections from a few hospitals when Forest sold their Cyclanfor under a different color. We were told that all we are doing is creating confusion.

[68] Q. Who told you that? A. It was one of two hospitals.

* * *

Q. When did you stop — I am saying Forest — stop selling the Cyclanfor in the various shades of green? A. A few months ago.

Plaintiff's Exhibit 144

Q. 1978? A. Yes. When we found resistance to the product.

* * *

[69] Q. Have you ever had occasion to discuss with your Inwood customers the color? A. We have received requests from some of our distributors, if there was a similarity to the color so they would have no problem selling it into stores or hospitals or whatever accounts they are selling to. Naturally we answered in the affirmative that the color was generically equivalent in the chemical structure and in the color of the capsule, also size and shape.

* * *

[82] Q. Mr. Field, you testified that Forest Laboratories had discontinued marketing its Cyclanfor capsules in their shade of green coloration.

Would you tell us why Forest discontinued such manufacturing and sale? A. Because the color was not acceptable to the hospital trade.

Q. What were you advised as to the lack of acceptability of this color from the hospital trade? [83] A. Some hospitals said that it would require re-education of the personnel in the hospitals, such as the nurses and the doctors and the registered pharmacists, and it was too much confusion for them to handle since the drug was always produced in the basic blue and red and blue colors.

* * *

Plaintiff's Exhibit 144

[84] Q. Do you use the same size tablets as Ciba-Geigy in the manufacture of the generic products? A. We use the same size, shape and color.

* * *

[85] Q. In connection with the hydrochlorothiazide tablets, do the different sizes denote different dosage strengths? A. They do.

* * *

[88] Q. Mr. Field, you mentioned the drug Prednisolone before, and on your price list you list a license under patent number. Is that correct? A. That is correct.

* * *

Q. From whom are you licensed to manufacture [89] Prednisolone? A. I previously stated: The Schering Corporation.

Q. What color do you make the 5 milligram size in? A. Prednisolone, 5 milligram? Peach color.

Q. Is that the same color and size as is used by the Schering Corporation? A. It's the same size, shape and color as their brand name product called Meticortelone.

Q. I notice that you are also licensed to manufacture a product generically known as prednisone tablets and make that in a white 5-milligram tablet.

* * *

Plaintiff's Exhibit 144

A. The answer is the same. We produce this product in the same size, shape and color as the brand product called Meticortelone. That is manufactured by the Schering Corporation.

* * *

EXHIBIT 145 — JOINT DESIGNATED EXCERPTS OF DEPOSITION TESTIMONY OF DARBY, RUGBY AND SHERRY BY JOSEPH ASHKIN, MAY 9, 1978

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

Civil No. 78-C

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., et al.,

Defendants.

Deposition of Defendants DARBY DRUG CO., INC.,; RUGBY LABORATORIES, INC.; and SHERRY PHARMACEUTICAL BY: JOSEPH ASHKIN * * * on Tuesday, May 9, 1978, at

* * *

[4] JOSEPH ASHKIN, residing at 1020 Seawane Drive, Hewlett Harbor. Long Island, New York, having been first duly sworn by the Notary Public, was examined and testified as follows:

* * *

Q. What is your position at Darby Drug? A. President.

Exhibit 145

Q. How long have you been president? A. About thirty years.

* * *

[5]Q. What is your business experience, Mr. Blackman? A. I am sorry, my name is Mr. Ashkin. Mr. Blackman was here previously. Let's keep the record straight.

My business experience, I have been in business for thirty years.

Q. You have been at Darby Drug for thirty years; is that correct? A. Yes. That is correct.

* * *

Q. What is your position at Rugby Laboratories, Inc.? A. President.

Q. How long have you been president of Rugby? A. Since its inception.

Q. When was that? A. About twenty years ago.

Q. Do you hold any positions at Sherry Pharmaceutical Co., Inc.? A. Yes.

* * *

[8] Q. Can you tell us for the record what the business of Darby Drug Company is, what does it do? A. Distribute pharmaceutical products.

Exhibit 145

Q. Has that always been its business? A. Yes.

Q. What is the business of Rugby Laboratories? A. To distribute pharmaceutical products.

* * *

[21] MS. DRISCOLL: A request was made in the request for production, also, for specimens of cyclandelate sold by Darby and Sherry. I ask you if you brought any of those with you?

MR. MARROW: My understanding is that Darby and Sherry sell cyclandelate in bottles with the name Rugby on the label.

MS. DRISCOLL: Is Mr. Marrow's understanding correct?

THE WITNESS: Yes.

[22] Q. In other words, are there no products sold by Sherry or Darby that have labels other than those shown on nine and ten? A. No.

Q. That is not right or that is right? A. It is right. The only label that we sell is Rugby and Ives, as well, as every other major manufacturer in the United States.

Q. Does Rugby sell Ives' Cyclospasmol? A. Rugby, no.

Q. Does Sherry sell Ives' Cyclospasmol? A. No.

Q. Does Darby? A. Yes.

Exhibit 145

Q. How long has Darby been selling Ives' Cyclospasmol? A. Ever since you brought it out.

Q. Did the other two companies ever sell Cyclospasmol? A. Yes. Wait a minute. I would like to correct that. Sherry does sell Cyclospasmol under the Ives name, I believe they do. I will check that in a second. (Pause) Yes. Sherry does sell Cyclospasmol.

* * *

[23] Q. Rugby does not? A. Rugby does not, no.

Q. Does Rugby sell only generic drugs? A. That is correct.

Q. Just so that we know for the record in connection with further questions, what is your understanding of what a generic drug is? A. A generic drug is that drug which is sold under its chemical name.

* * *

Q. Do you know of any practice in the drug trade of listing generic products in the left-hand column and national branded products in the right-hand column as a custom? In other words, the opposite of what you do, do you know of any custom in the trade of other distributors who reverse your order and — A. I don't understand that.

MR. MARROW: Is that a custom of putting [24] generics on the right and brand names on the left?

Exhibit 145

THE WITNESS: The position is strictly the choice of the person —

Q. Your answer to my question is there is a custom is no? A. It is strictly the choice of the person preparing the catalogue, and since there are only four positions that you can put it, top, bottom, left or right, it is bound to appear as a duplication, more than one will be in the left and more than one will be in the right and more than one will be on the top and more than one will be on the bottom, since more than four people are doing this.

Q. On Page 9 of Ashkin Exhibit 1, and referring to the box headed "Cyclandelate," is it the custom of Rugby in its catalogues to designate the color of the generic drug that it offers? I notice that it does give a color, but is that a custom of the company? A. There is no rule which states that it has to be done on every single product. It is done strictly as an informational procedure.

Q. Do you ordinarily give the color of the [25] generics, what you call the Rugby generic brand? A. Yes.

* * *

Q. Opening Ashkin Exhibit 9, do you know whether when products are sent out of Rugby, for example, or the other two companies under this label, there is a package insert usually in the product? A. I am not familiar with the manufacturing procedures on these products.

Q. When you send them out from Rugby or [26] Sherry or Darby under this label would a bottle such as Exhibit 9

ordinarily have an insert in it? A. Are you refer
cyclandelate itself or are you referring to all products?

Q. I am referring to Exhibit 9. A. Counsel, we b
products under a standard form, the Food and Drug g
is required by law. It is the obligation of the manufac
meet that law. Part of that law also states that once we b
seal on the package we have broken the integrity of the
and broken the law. We do not make the specificatio
what goes into the bottle or on the bottle. We buy a
package.

* * *

[28] Q. Is there any other way in which you could
it is a capsule distributed by Rugby; if you had not
remove it from Exhibit 9?

* * *

A. No.

* * *

[29] Q. If you had not seen me take it out of th
would you have known who distributed Exhibit 12?

Q. In connection with Exhibit 12, which is the blue
capsule of 400 milligram cyclandelate, is your answer
as with the plain blue 200 [30] milligram capsule — nan
it has always been sold by the three companies in t
without printing on the capsule? A. It has nev
imprinted.

Exhibit 145

* * *

[33] Q. Do you know if either company ever placed or attempted to place a bid with any government agency in order to sell cyclandelate? A. I would say no.

* * *

[34] Q. Referring to Rugby, is the generic cyclandelate sold by Rugby? Does it represent a small or a large portion of Rugby's business? A. Infinitesimal in the overall picture. No one product is that important.

Q. What about Sherry? A. The same way.

Q. And Darby? A. The same way.

* * *

Q. Referring to Ashkin Exhibit 7 for identification, which is a 1977 Sherry catalogue, specifically to page 3, what is the basis, to your knowledge, for the [35] statement made on page three that Sherry's drugs are "guaranteed to meet all Federal and state regulations"?

* * *

Q. Can you tell me what that means? It's in the catalogue, and I assume that you know what it means. That is your company.

MR. MARROW: Excuse me. There are two — A. Let's restrict ourselves to the question without the side issues of sarcasm. If you will repeat your question, I will try to answer it.

Exhibit 145

MS. DRISCOLL: Would you read back the question.

A. (Continuing) A simple statement of fact from the manufacturer, extending to my company a guarantee that any product he makes for me on my label meets the standard of quality of the Food and Drug Administration.

* * *

[40] Q. Insofar as Darby is concerned, do you know the basis for the statement that plaintiff knew of its acts for a "substantial period of time"?

* * *

Q. Are you aware that that statement was made on behalf of your three companies, sir? A. Yes.

Q. Do you know the basis for the statement that plaintiff knew of Darby's acts for a substantial period of time? A. Since it has been going on for a number of years.

Q. What has been going on? A. Our advertising of the product under the generic name, not only ourselves but many others.

* * *

[42] Q. Insofar as Rugby is concerned, when did Rugby first begin selling generic cyclandelate? A. Again the date is not specific in my mind.

Q. Is there any approximation? A. A few years. I imagine.

Exhibit 145

* * *

Q. Did you personally play any role in connection with the decision by Rugby to sell generic cyclandelate? A. The decision making is done in committee.

Q. Are you part of the committee? A. Yes.

Q. Or were you part of the committee? A. Yes.

* * *

[43] Q. Can you describe to the best of your recollection the circumstances surrounding Rugby's decision to sell generic cyclandelate? A. The product was offered to us by the manufacturer and we were advised by the manufacturer that this was a Paragraph 14 drug. It would be offered to us under [44] the standard form food and drug guarantee.

* * *

[46] Q. I show you a box and the heading of the box is the word S-p-a-s-m-o-l Spasmol. A. Yes.

Q. Did you play any part in the selection of that word? A. No. That was the name that was on the product when we got it from Sherry.

Q. When you say "on the product," do you mean on the actual labels? A. On the label.

* * *

Exhibit 145

[47] Q. Do you currently use the word "Spasmol" in any of your catalogues? A. No.

Q. When did you stop, if you know? A. When it was called to my attention by one of the clerks in inventory.

Q. Can you describe these circumstances and about when this happened? A. I don't recall the exact date. But it was pointed out that the word "Spasmol" was no longer relevant since [48] we were shipping it under the generic term only.

* * *

[52] Q. For what purpose are the references "comparable to Cyclospasmol" and "similar to Cyclospasmol" utilized in the two catalogues that I have just referred to?

* * *

A. Common trade practice.

Q. What trade? A. The pharmaceutical trade.

* * *

[54] MR. MARROW: Are the generic products [55] sold in the same colors?

THE WITNESS: Yes.

Q. Is there a reason for this, to your knowledge? A. That is the way the manufacturer supplies it to us.

Exhibit 145

Q. Have you ever purchased cyclandelate capsules in any colors other than blue, for 200 milligram — A. You asked that before.

Q. — and blue-red? A. We are going over the same ground again.

Q. I don't believe that I asked this question. Forgive me if I have, but I want to make sure that it is in the record.

Have you ever purchased those capsules in any colors other than blue or blue and red? A. No.

* * *

[67] Q. I ask you once again, because I don't believe that that was responsive to my specific question: For what purpose is the national brand Cyclospasmol listed in the chart on page two of the current Rugby catalogue, next to a column which says "cyclandelate," and the heading of that column is "Rugby Generic Brand"? Why is Cyclospasmol listed there, sir? A. It is listed there as a frame of reference.

* * *

[68] Q. Apart from this litigation, are you aware of any instances in which generic cyclandelate distributed by any of the three companies that you are testifying for has been illegally substituted for a prescription in which Cyclospasmol was called for in a pharmacy? A. Are you asking me if I know of anybody who did something illegal?

Q. In connection — I want to know if you know of any substitution other than what you may have learned about in

Exhibit 145

connection with this specific litigation. A. Only as to what I have learned here.

Q. Do you ever visit pharmacists, sir? A. No.

Q. Does someone in your organization have that as a responsibility? A. No.

Q. Are sales to pharmacists, therefore, pretty much handled in the Darby-Sherry organization by the distribution of catalogues? A. That is correct.

Q. Is there any other way in which those two [69] companies attempt to attract business from pharmacists? A. No.

* * *

[74] Q. In your experience in the drug industry, did you ever have occasion to visit pharmacies in the line of your employment? A. No.

Q. Mr. Ashkin, I have not yet received, but it is not due until next Monday, reply papers in connection with the motion now pending in court in this case.

I am somewhat at a disadvantage, but I don't want to have to call you back after I receive the papers.

Is it the contention of Rugby, Darby and Sherry that they will be injured if they are enjoined from selling cyclandelate products in the colors blue and blue-red? A. Yes.

Exhibit 145

Q. In what way, would you tell us, do you claim that the companies would be injured? A. You will be forcing us to market what we call an inferior product. We will be destroying the quality, the safety and the effectiveness, putting those in jeopardy.

Q. In other words, you are testifying that [75] a change in color would destroy the quality, safety and effectiveness? A. Right.

Q. And why is that, sir? A. You would be forcing us to market an inferior product because immediately this product was given to a pharmacist, he would question it as to whether it is the product so-labeled on the face of the bottle. You would also throw a severe amount of doubt into the patient's mind as to whether it is cyclandelate. Then the effect of that would be that the patient would doubt the effectiveness of the product. The integrity of the product all the way is destroyed.

Q. What is the basis for your conclusion as to what pharmacists would do if you sent them cyclandelate in a different color? You previously testified that you never visited pharmacies in your employment. What is the basis for that assumption on your part? A. I do believe that the telephone is still in existence. Every time the pharmacist will receive a capsule that is even slightly off color, as received from the manufacturer, the phone will ring and he will demand to know is the product what it is supposed to be.

[76] Q. Has that happened at any of the three companies? A. Yes.

Q. Do your people have instructions as to what to tell pharmacists should this occur? A. Yes.

Exhibit 145

Q. What are those instructions? A. To reassure them that while the shade may be slightly different, it is the same and that to return it to us immediately so that we can return it to the manufacturer.

Q. How often, if you know, would your three companies receive communications like this from the phramacists? [sic] A. We keep no scorecard on that.

Q. Does it happen often, seldom? A. In my years in the field I have had it happen numerous times.

Q. What do you mean by your years in the field? A. I have said that I have been in this field 35 years.

* * *

[77] Q. Getting back to your previous testimony, what is the basis for your testimony that a change in color could create doubt in a patient? A. Well, it is twofold. First is experience in the field, speaking to pharmacists who, whenever they receive a tablet in which the shading is not particularly correct, as I said, they feel that there are many variations of a particular color and shadings, I should say, they will immediately call us and ask us if the product is what it is supposed to be.

Q. My question related to patients. [78] A. Their anxiety, as they explained it to us, stems from the fact that they will not put something into the patient's hands which is not the exact same color, size and shape. The second part of the answer is that, it is based upon my own personal experience as to how I would feel if I received something from the pharmacist which was other than in a standard color and shape, I would immediately call him and ask him if he had sent the right thing.

Exhibit 145

Q. You would call? A. Correct.

* * *

Q. Have any of the three companies had occasion to change, during the period of distributing a generic drug, the color of the drug in your experience with those companies? A. Not to my knowledge.

Q. So, you have never in the company had firsthand knowledge of what the consequences might be; is that correct? A. Not within our company, but in general trade practice, yes.

Q. What is the basis of your statement as to [79] the general trade practice, do you know of specific instances where colors have been changed by other companies or is this more of a general statement? A. In the instance of some of the major companies who have tried to create a branded generic with a new color on a particular product, the reception of the product at the pharmacists' level has been so poor that in the future products which they came out with, they did match the color.

Q. Can you tell me specifically what product you are referring to or products that you are referring to? A. Quite easily for you to determine that by looking at certain products in the Lederle generic line. You will note that in their initial presentations they attempted to create a so-called high priced generic specialty, even though their products were purchased in the exact same place that I bought them, they were being marketed at three or four hundred per cent over and above my price and that the color fell flat. It was not accepted by either the

Exhibit 145

pharmacist or the general public, the layman who would receive the end product; that the products that they are currently bringing out are in the color, in the size, and in the shape —

[80] Q. Of what, the national brand marketed? A. Of the national brand.

* * *

Q. You mean quite a few are doing what you do, which is copy the brand name leader and color? A. In color, size and shape.

* * *

[81] Q. You are saying that you think it is important that, for example, cyclandelate, I gather that this is your testimony, should be sold in the same color by everyone; is that what your contention is? A. No. It is my belief that all generics should be sold in the same color.

* * *

Q. Do you know of any generic products currently on the market in a color that — of the same chemical composition but which are sold in different colors? [82] A. Yes.

Q. Which ones are you aware of? A. No specific one. In particular when it is generally created in another color, to justify a substantial increase in the generic price.

* * *

Exhibit 145

Q. In your opinion as someone who has been in the drug field for many years, do you believe that if a pharmacist desires illegally to substitute a generic when a brand name is called for on a prescription, that it would be easier for him to get away with it if the color of the generic is the same as the brand name product color? A. That doesn't make —

MR. MARROW: I would stipulate that it is.

Q. Fine.

* * *

Do you know whether there are [83] pharmacists who prefer to deal in brand name products as opposed to generics? A. I imagine that there are. However, I would point out to you that there are certain states now and that the public trend is toward generic formularies which are now in some 40 states, may of which stipulate that the pharmacist has no choice and must supply the lowest available generic product acceptable for reimbursement on third-party payments.

Q. Do you know if cyclandelate is in any formularies? A. I don't know of any one particular product which is in any particular formulary since each formulary covers the gamut of the red book which runs several hundred pages as a listing of products.

* * *

Q. Do you know from your experience in the drug trade again whether there are physicians who prefer to prescribe a brand name product as opposed to [84] a generic product? A. That you can stipulate to.

Exhibit 145

Q. In other words, yes? A. Of course.

Q. Are there also patients who prefer to receive such a brand name product as opposed to a generic? A. I would assume that there are.

* * *

Q. Referring to Ashkin Exhibits 9 and 10, which are containers for 100 capsules of 200 or 400 mg. cyclandelate capsules, do the three companies distribute cyclandelate in any other quantities? A. Not to my knowledge.

Q. In other words, they are all the 100 size? A. Maybe 500. I don't know. I would have to check that.

Q. Would that show in your catalogue? A. Yes. It would be in there.

* * *

A. Bottles of 500 on the 400 mg. Hundreds, 500's and thousands.

[85] Q. In other words, they are sold in three sizes, 100, 500 and 1000; is that correct? A. Yes. That is correct.

* * *

Q. If a pharmacist purchased in quantities of 1,000, so that he had a large bottle of 1,000 cyclandelate capsules, can you describe for us from your general experience in the trade what the pharmacist would do with that bottle? Does he use the large

Exhibit 145

bottle [86] and pour out capsules from time to time to fill a small bottle for a prescription? A. That is correct.

Q. Is the same true of the 500 size? A. Yes.

* * *

Can you tell us for the record what you mean by the statement that "Insofar as color is concerned that the color is a functional feature of the products"? [87] A. Yes.

Q. What does that mean? A. The functional features that both the pharmacist and the ultimate consumer, the patient, identify the product by its color. Given another color, they would question the integrity of the product.

Furthermore, that would put us in the class of offering them an inferior product if we were to tamper with the color.

Q. When Rugby and Darby decided to sell cyclandelate products, did you believe at that time, and we unfortunately don't have a date — did you believe at that time that the color of Cyclospasmol capsules were functional? A. We didn't question that feature. The product was offered to us by the manufacturers in the specific color. The manufacturers being very well aware of the same information that I just gave to you here. It was never offered in any other color than that.

* * *

[88] Q. How would one, in your opinion, since this is your answer, come to recognize color as a functional feature, is that through long use? How does that come about? A. It comes about that the pharmacist has seen it in one particular color for

Exhibit 145

a number of years, that it is often not only by myself
generic [89] people in the same color as well as
Company.

Q. In other words, this is not an instantaneous t
first time you sell it people don't recognize it as being fu
is that correct? This only comes about after
years? A. Having received one prescription, the sec
comes to hand and it is a different color, immediately
question of whether a person is becoming a first time u
product or has been a long time user of the product.

[90] Q. But, a pharmacist, I believe you testified,
recognition. A. He recognizes —

Q. Over some years. A. He recognizes that Cycl
comes in this particular color.

* * *

[93] Q. Turning to page 5 of the answer, p
23: What is the basis for a claim that any compa
defendants may have made with respect to cyclandel
Cyclospasmol are accurate? A. What is the basis fo

Q. Yes. A. Various chemical tests that we have
the two products.

Q. Who is "we"? A. Meaning the manufac
course. This is the manufacturer.

Q. Not the three here.

Exhibit 145

[94] Q. You stated earlier today that the sales of cyclandelate by the various three companies are infinitesimal, I believe your words were.

Has that always been true over the course of time that the cyclandelate has been sold, to your knowledge? A. I believe that the word "infinitesimal" in the context that I used it, was not in the same context that you used it. You must understand that we distribute some 25 or 23,000 various products.

Q. Who is "we"? The three? A. Darby and the three others, and the other two companies. They distribute that many products. There is no one product which can be considered as representing an abnormal part of our business.

What is involved here is a principle for which we are not prepared to give up.

Q. I believe that we have a question pending. A. It was nonexistent at one point until we began to sell it.

Q. It's always been a small part of the business? A. It represents a small part, yes. But it is a [95] part.

* * *

[97] Q. I notice in the Darby catalogue that the representation is made that the generic cyclandelate is similar to Cyclospasmol, and in the Sherry catalogue that Spasmol is comparable to Cyclospasmol. But, I find no such specific reference in the Rugby catalogue. Was that intentional? A. No. Strictly editorial.

Exhibit 145

Q. It was not the result of a conscious corporate decision? A. Correct.

Q. Do you know whether any Rugby catalogues in the past have ever specifically made the claim of similarity or comparability of cyclandelate to Cyclospasmol? A. I assume so.

Q. In the current Darby catalogue at Page 21 under the reference to cyclandelate, there is an indication of the color of the 200 milligram capsule, but there is no indication of the color of the 400 milligram capsule. [98] Is that once again — A. Strictly editorial. A question of space available.

* * *

Q. Why is color mentioned at all in your catalogues?

MR. MARROW: That was asked and answered. A. I believe that that was asked earlier and was answered.

Q. Why is it mentioned in catalogues specifically that go to physicians as opposed to wholesalers or pharmacists? A. No particular reason. Strictly editorial. You asked why it is in one and not in the other two, but it is [99] in the other.

Q. No. I had a slightly different reason. The question was directed to, what is the reason, if any, why you would list color in a physician's catalogue? A. To assist him to understand the product. It is an editorial choice.

* * *

DEFENDANT'S EXHIBIT 12 (INWOOD) — LIST OF COMPANIES MARKETING CYCLANDELATE PRODUCTS

COMPANIES MARKETING CYCLANDELATE PRODUCTS

Cumberland Pharmacol Co., Inc.
327 Baltimore Avenue Box 88
Cumberland, MD 21502

200mg. Capsules

Dixon-Shame, Inc.
1518-22 Seller St.
Philadelphia, PA 19124

200mg. Tablets

Generix Drug Corporation
P.O. Box 1967
Hollywood, PL 33020

200mg. Capsules

Lannett Co., Inc.
900 State Road
Philadelphia, PA 19136

200mg. Capsules

Defendant's Exhibit 12 (Inwood)

Midway Medical Co.
103 Samson Street
Glasgov, KS 42141

200mg. Capsules

H.L. Moore Drug Exchange, Inc.
370 John Downey Drive
New Britain, CN 06050

200mg. Capsules T.R.

400mg. Capsules T.R.C.

Paramount Surgical Supply Co.
164 Union Street
Northvale, NJ 07647

200mg. Capsules

400mg. Capsules

Pharmecon, Inc.
23550 Haggerty Road
Framington, MI 48024

200mg. Capsules

Defendant's Exhibit 12 (Inwood)

Premo Pharmaceutical Labs, Inc.
111 Leuning Street
South Hackensack, NJ

200mg. Capsules

Rugby Laboratories
16 Nassan Avenue
Rockeville Centre, NY 11570

200mg. Capsules

400mg. Capsules

Spencer-Mead, Inc.
270 W Merrick Rd
Valley Stream, NY 11582

200mg. Capsules

400mg Capsules

West-Ward Inc.
745 Eagle Avenue
Bronx, NY 10456

200mg. Capsules

Defendant's Exhibit 12 (Inwood)

Wolins Pharmacal Corp.
75 Marcus Drive
Melville, NY 11746

200mg. Capsules

DEFENDANT'S EXHIBIT 63 (PREMO) — JOINT DESIGNATED EXCERPTS OF DEPOSITION TESTIMONY OF RUDOLPH F. PRINZ, JANUARY 14, 1980

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
CIVIL ACTION NO. 78-372

IVES LABORATORIES, INC.

Plaintiff

vs.

DARBY DRUG CO., INC., et al.

Defendants

DEPOSITION OF RUDOLPH F. PRINZ

* * *

[3] Q. Would you state your name and spell it for the record, please? A. Rudolph F. Prinz. R-U-D-O-L-P-H, initial F., P-R-I-N-Z.

Q. Mr. Prinz, where do you reside? A. 463 Hogarth Avenue, in Niles.

Q. That's Niles, Ohio? A. Niles, Ohio — excuse me.

Q. What is your occupation? A. Pharmacist.

Q. Could you briefly sketch your educational background for me? A. Professional education?

Defendant's Exhibit 63 (Premo)

Q. Yes. A. Attended Ohio Northern University, received a Bachelor of Science in Pharmacy in the years 1953. After a short interim in the service, attended both Youngstown State and Hiram University for furthering courses [4] in biology, physiology and advanced chemistry.

Q. Are you licensed to practice pharmacy in the State of Ohio? A. Yes, I am.

Q. And other states? A. I have not reciprocated my license.

Q. Are you appearing today at this deposition on behalf of Calvin's Pharmacy? A. I believe so. To the best of my knowledge, I am.

Q. What is your relationship to Calvin's? A. I'm the owner.

* * *

[16] MR. RAUBICHECK: Why don't we mark this a group exhibit? I would like the reporter to mark as Plaintiff's Group Exhibit 7, five of the copies of Cyclospasmol prescriptions which were produced by Mr. Prinz. The sixth one which was for Cyclospasmol tablets, 100 milligrams, I'm going to return to Mr. Prinz because the 100 milligram dosage form is not the subject of this action.

* * *

Q. Now, just so that I understand it correctly, Mr. Prinz, could you identify again Plaintiff's 7? A. You want them one by one of just —

Defendant's Exhibit 63 (Premo)

Q. Just in general what they constitute. A. This is a copy of a written prescription by a physician for a patient Charles Jacobs, dated —

[17] Q. In other words, just in general what do these documents constitute? A. These are copies of prescriptions that have been filled at Calvin's Pharmacy that have been researched, pulled from the file, copies made and presented today.

Q. Now, do these copies of prescriptions constitute copies of all prescriptions within your records for patients who have had prescriptions filled for Cyclospasmol or are they representative? A. These are the total prescriptions that we are now actively filling and they go back, some of them, as far as two or theree years. To the best of our ability, those that we were able to produce. To go through prescriptions one by one for hours and hours, it's almost an impossible situation.

Q. These are your current customers? A. These are the current customers on Cyclospasmol.

* * *

[23] Q. Mr. Prinz, Plaintiff's Exhibit 10, I would ask you if you could identify that, please.

MR. COBRIN: I think you ought to identify on the record what that is, Charlie.

MR. RAUBICHECK: It's an item that appears to be a [24] bottle, produced by the witness pursuant to Item 3 of the Schedule A, and I'm asking the witness to identify

Defendant's Exhibit 63 (Premo)

it. A. Exhibit 10 represents a bottle of Cyclandelate capsules 400 milligrams, manufactured by Pharmadyne Laboratories, purchased from Bioline Laboratories by us on October 19, 1979.

Q. Bioline? A. Yes, Bioline Laboratories in New York.

* * *

Q. Mr. Prinz, does Calvin's, other than Plaintiff's 10, have any other Cyclandelate capsules in stock which it purchased from Bioline which were made by Pharmadyne? A. Yes, I have another bottle of a full 500 on my shelf.

* * *

[25] Q. Okay, the next bottle, Plaintiff's Exhibit 11, I'll ask Mr. Prinz to identify it. A. Exhibit 11 is a partially filled bottle labeled "Cyclospasmol 200 milligrams capsules" cyclandelate, purchased by Calvin's Pharmacy from Scherer-Thompson Inc., Auburn Heights, Michigan, manufactured by Cord Laboratories, Bloomfield, Colorado.

* * *

[28] Q. The generic cyclandelate that you purchased from distributors other than Bioline and Scherer-Thompson, was that bought in 200 and 400 milligram dosage forms? A. Yes sir.

Q. What were the colors of the 400 milligram dosage form that you purchased other than from Scherer-Thompson and Bioline? A. They were all the same color.

Q. What colors were those? A. A red and a blue.

Defendant's Exhibit 63 (Premo)

Q. And how about the 200 milligram? A. Totally light blue.

* * *

[29] MR. RAUBICHECK: Well, I would like to mark as Plaintiff's Exhibit 12, two items which have been produced by Mr. Prinz.

[30] (Plaintiff's Exhibit 12 Marked for Identification)

Q. I'll ask Mr. Prinz, again, if you could identify those. A. Yes. These are empty samples of blister packs used in a packaging machine within our pharmacy.

Q. Now, does Calvin's use blister packs similar to those — I should say identical to those in Plaintiff's Group Exhibit 12, to package cyclandelate? A. At the present time we do.

Q. Have you brought with you any blister packs which contain cyclandelate in them? A. Yes.

MR. RAUBICHECK: I would like the reporter to mark these two items which have just been handed to me by Mr. Prinz as 13A which would be the 200 milligram and 13B which would be the 400 milligram.

(Plaintiff's Exhibits 13A and 13B Marked for Identification)

Q. Could you identify Plaintiff's Exhibit 13A for the record? A. Yes. This is a unit dose package prepared at Calvin's Pharmacy that contains one dose of cyclandelate 200 milligrams.

Defendant's Exhibit 63 (Premo)

[31] Q. And could you identify Plaintiff's 13B for the record? A. 13B is a unit dose strip pack prepared at Calvin's Pharmacy of one dose of cyclandelate 400 milligram.

Q. Now, Plaintiff's Exhibits 12, 13A and 13B, you have described as blister — as unit dose packs? A. That's right.

• • •

[32] Q. Mr. Prinz, I show you an item which is marked as Plaintiff's 14 and I would ask you if you have ever seen it or anything like it before. A. Is this what you are referring to as a blister pack?. Q. Yes. A. In your terminology of a blister pack rather than a unit dose pack?.

Q. Right. If you have seen it or anything like it, could you describe and identify it? A. That's what I was planning on doing. Exhibit 14 represents a so-called blister pack prepared by Calvin's Drug Store, July 9, 1979. This particular package or packaging is used exclusively in an emergency drug cupboard. It so designates that it contains Cyclospasmol with a capital letter "G", designating the generic equivalent. It's 400 milligrams, the lot number of the bottle taken from, and the expiration of the dosage form enclosed.

Q. Was the packaging of the capsule Plaintiff's Exhibit 14 prepared by Calvin's? A. Yes. It has our name on it.

• • •

[33] Q. So that the cyclandelate Calvin's packages in the package in Plaintiff's 14 is used for emergency administration only? A. Yes, sir.

Defendant's Exhibit 63 (Premo)

* * *

[40] Q. Mr. Prinz, I show you a document marked as Plaintiff's 17 and ask you if you could identify that. A. It is a catalogue put out by Spencer-Mead from Valley Stream, New York. This is their complete catalogue of drugs, pharmaceuticals, and supplies available.

Q. And I call you attention to Page 5 of Plaintiff's 17 and I ask you if the drug cyclandelate is listed on Page 5. A. Yes, it is listed on Page 5 — cyclandelate.

Q. Have you ever purchased cyclandelate from Spencer-Mead pursuant to that catalogue? A. I would assume I have. I have no way to say I haven't.

Q. Do you know who manufactures the cyclandelate distributed by Spencer-Mead? A. I don't know, but if I ordered a bottle — they are a national distributor and it would have to be labeled by law on the side of the package as to who manufactured it for their distribution.

(Plaintiff's Exhibit 18 Marked for Identification)

Q. The next item is a document marked as Plaintiff's 18 and [41] I'll ask Mr. Prinz if he can identify it. A. This is a price list for drugs and over-the-counter specialties put out by Scherer-Thompson, Auburn Heights, Michigan.

Q. And on Page 2 of Plaintiff's 18, is the drug cyclandelate listed? A. Yes, on Page 2 the drug cyclandelate is listed.

Defendant's Exhibit 63 (Premo)

Q. Did Calvin's purchase the cyclandelate ca
Plaintiff's Exhibit 11 pursuant to the Scherer-T
catalogue which has been marked as Plaintiff's 18? A
bottle designates it's from Scherer-Thompson, the
ordered through them, yes sir.

(Plaintiff's Exhibit 19 Marked for Identificatio

Q. The next item is Plaintiff's Exhibit 19 and I'll
you would identify that, please. A. Plaintiff's 19 is a
of drugs available from Diacin Pharmaceuticals and G
Ferndale, Michigan.

Q. And on Page 6 of Plaintiff's 19, is the drug cy
listed? [42] A. Yes. On Page 6 cyclandelate is listed

Q. Has Calvin's ever purchased any cyclandel
Diacin? A. No. sir.

(Plaintiff's Exhibit 20 Marked for Identificatio

Q. I have asked the reporter to mark the next do
20 and I'll ask Mr. Prinz to identify it. A. Exhib
catalogue put out by Generix Drug Corporation, H
Florida.

Q. On Page 5 of Plaintiff's Exhibit 20 is cyclandel
the drugs listed? A. Yes, on Page 5 of Exhibit 20
cyclandelate is listed.

Q. Has Calvin's ever purchased any cyclande
Generix? A. No.

Defendant's Exhibit 63 (Premo)

Q. Do you know which company makes the cyclandelate distributed by Generix? A. As repeated before, these are distributors. If they did not manufacture the product, it would be labeled or marked by law on the label.

Q. Now, you testified that Plaintiff's Exhibits 17 through 20 are representatives of —

* * *

[43] (Plaintiff's Exhibit 21 Marked for Identification)

A. Exhibit 21 is a generic price list and order form from Michigan Pharmacal Corporation, Ferndale, Michigan.

Q. On the bottom of the first page of Plaintiff's 21 there is a circle around a notation. Does that notation indicate that Michigan Pharmacal offers cycylandelate? A. Yes, on the header page this indicates cyclandelate is available.

Q. And has Calvin's ever purchased generic cyclandelate from Pharmacal? A. If I had it would be some time ago.

Q. Do you recall if you had purchased it who made the generic cyclandelate distributed by Michigan Pharmacal? A. No, I don't.

Q. You testified a few moments ago that Exhibits 17 through 21 are representative catalogues which Calvin's has within its possession which contain reference to generic cyclandelate or Cyclospasmol. [44] A. Right.

* * *

Defendant's Exhibit 63 (Premo)

[45] Q. Okay, with respect to the prescriptions, the five prescriptions in Plaintiff's Group Exhibit 7, were those prescriptions filled by you personally? A. Originally or refilled?

Q. Both, if you know. A. Three were filled by me originally, two were not.

Q. Are these all refills? A. Those are original orders. I did not photostate the backs because there is no way it would correlate the front. Each time a prescription is refilled it is dated, stamped, and initialed by the pharmacist that filled it.

Q. Do you know for each of these prescriptions in Plaintiff's Exhibit 7 whether for any of those prescriptions a [46] generic dosage form of cyclandelate was dispensed as opposed to Cyclospasmol? A. Yes.

Q. An what is your answer? Was a generic dispensed for each of those? A. Not each.

Q. For which were Cyclospasmol dispensed and for which were generic cyclandelate dispensed? A. Generics were dispensed on each except this one written in the doctor's handwriting "DAW".

* * *

[52] Q. Okay, to your knowledge does the dispensed as written requirement that applies to prescriptions which are filled in your pharmacy also applied to orders that would be filled from physicians in nursing homes? A. It does not. Under the Ohio Revised Code, hospitals [53] nursing homes, and

Defendant's Exhibit 63 (Premo)

convalescent centers are exempt unless the physician writes "DAW".

* * *

Q. Could you explain what you mean by "exempt" in your last statement? A. Okay, what I mean by exempt, is that if you came to me with a prescription for Cyclospasmol, the Ohio Revised Code states that if I have a generic available at a lesser cost, then I'll offer it to you — not mandatory, but it's a three-part situation. In other words, I offer it to you telling you that I have the generic available for the order that your doctor has written. That's in lieu of the doctor not writing — and it has to be written in Ohio — "DAW" or dispense as written, in his handwriting. No blocks or checks or anything else. I then, if you are interested, then I'll price for you the prescription as far as the name brand and I'll price for you the prescription as of the generic, keeping [54] in mind that the differential in the price, your acquisition price or cost price of the prescription, must be at least the cost differential of the two products to me. Then you make the decision whether you want the prescription filled generically or not. If you so desire or designate you want the generic used, then we fill it with the generic, mark the prescription that the generic has been used, and that is your price and when I'm talking about the exemption for hospitals, nursing homes, and convalescent centers, I don't have to go to each patient and say, "Do you want this filled generically." All I have to do is pass on to them the cost between the generic and the name brand.

* * *

Defendant's Exhibit 63 (Premo)

Q. Turning your attention for a moment to Plaintiff's Exhibit 13A, can you tell from looking at that exhibit whether [55] the capsule contained in the package in Plaintiff's 13A is Cyclospasmol 200 milligrams? A. You mean the branded name Cyclospasmol?

Q. No, I mean Cyclospasmol — right. Q. This is cyclandelate.

Q. So that the capsule in Plaintiff's 13A is not Cyclospasmol, the brand name product or drug? A. It's not the branded name drug. It's the generic equivalent of the branded name drug, which is cyclandelate.

Q. How do you know that? A. Because it does not have the identification marks of Ives on it.

Q. What are the Ives identification marks for Cyclospasmol 200 milligrams? A. I have to open one of theses. They are all the same.

MR. RAUBICHECK: Let the record show the witness is opening Plaintiff's Exhibit 9.

A. Printed on a two-part light blue capsule in script would be written the word "Ives". On the other part of the capsule would be their product identification number. The capsule I'm holding is indicated as [56] 4124, which under the N.D.C. No. 4124 would be the identification of Cyclospasmol 200 milligram, manufactured and sold by Ives.

MR. COBRIN: So the record is complete, I think I would want to note that the witness has taken a capsule out of the

Plaintiff's exhibit and held it in his hand and looked at it while he answered the question.

THE WITNESS: Right.

* * *

Q. Okay, turning your attention again to Plaintiff's Exhibit 13A, can you tell from looking at that exhibit if there are any marks on the capsule in Plaintiff's Exhibit 13A? A. Yes, I can rotate it. There are no identifying marks at all.

Q. Turning your attention to Plaintiff's Exhibit 13B, looking at Plaintiff's 13B, can you tell me whether the drug, I mean the capsule in 13B is Ives's Cyclospasmol? A. No. This is a capsule of cyclandelate 400 milligram.

[57] MR. RAUBICHECK: And let the record reflect that the witness has opened Plaintiff's Exhibit 8 and is holding a capsule from Plaintiff's Exhibit 8 in his hand.

* * *

Q. Plaintiff's Exhibit 14 — will you take a look at it, Mr. Prinz, and tell me whether or not that capsule is Cyclospasmol? A. This is cyclandelate both by identification and the labeling on the package which indicates Cyclospasmol "G", which represents the generic or cyclandelate.

Q. Are there any markings on the capsule in Plaintiff's 14? A. No sir.

[58] Q. Turning to Plaintiff's Exhibit 15, by looking at it can you tell whether the capsule in Plaintiff's 15 is Ives's

Defendant's Exhibit 63 (Premo)

Cyclospasmol? A. The capsule in Exhibit 15 is cyclandelate, as marked on the label.

Q. It is a generic version of cyclandelate? A. It is cyclandelate.

Q. It is not the Ives product? A. It's not Ives name branded Cyclospasmol.

Q. Are there any markings — A. There are no identifying markings on Plaintiff's 15.

Q. If you would turn and take a look for a moment at Plaintiff's 13A, 13B, and 14 and 15, Mr. Prinz, and you look on the back of each of the packages in those exhibits, do you know why the name Cyclospasmol is on the packages of each of those exhibits?.A. Why it is?

Q. Uh huh. A. Because it's a common identifying name for the chemical drug cyclandelate.

Q. Could you explain what you mean by "common identifying [59] name"? A. It's a name that probably most people would be familiar with — both professional and laymen — as to the medication so enclosed in the capsule.

Q. You testified a few minutes ago, Mr. Prinz, that Calvin's has not filled a prescription within the last two years for generic cyclandelate which was written for cyclandelate as opposed to Cyclospasmol. A. I said to the best of my knowledge I haven't.

Q. To the best of your knowledge. If that is the case, what is the basis for your statement that lay persons and medical persons would associate the drug cyclandelate with the name

Defendant's Exhibit 63 (Premo)

Cyclospasmol? A. I would assume that originally or whenever Ives' Laboratory received an authorization from the Food and Drug Administration to market cyclandelate under their branded trade name of Cyclospasmol, and this product was detailed and presented to the medical profession and made available through pharmacies to the patients when the doctors ordered it.

Q. When Calvin's packaged the capsules in Plaintiff's [60] Exhibits 13A, 13B, 14 and 15, were you or anyone else at Calvin's mistaken that the generic product which was being packaged was Cyclospasmol? A. No.

Q. You were not confused as to the identify? A. No.

Q. Who caused the name Cyclospasmol to be imprinted on Plaintiff's 13 through 15? A. I did.

Q. Were you or anyone else at Calvin's told by anyone that it was permissible to package generic cyclandelate labeled Cyclospasmol? A. My interpretation as far as the Ohio Revised Code, as far as packaging and labeling as indicated — and I don't know which Federal it is — but where Ives uses their branded trade name such as Cyclospasmol in identifying their product they have to print in half-size print underneath the generic equivalent or the generic name of the product they are identifying with their name and their name only.

MR. COBRIN: Would you please read that last [61] question and answer?

(The last question and answer was read by the reporter)

Defendant's Exhibit 63 (Premo)

Q. Do you construe that requirement that you have just testified about to apply to distributors or sellers of cyclandelate other than Ives? A. My interpretation of the law, when I put this package out —

MR. COBRIN: Can you identify the package you're referring to? A. Yes, Exhibit 13B. When Exhibit 13B is packaged by me, it's packaged with the name "cyclandelate" in one size print and with the strnegth [sic] of the dosage and the dosage size — 400 milligrams. Then in a smaller half-size print the common name, or Cyclospasmol.

Q. Now, you say that to your understanding that's permitted under Ohio law? A. When I called the Ohio State Board of Pharmacy — as you can see, package 13B and package 15 both contain doses of cyclandelate 400 milligrams, and there are two different sizes of strip. One is a film and one is an aluminum foil seal. We called the Ohio State [62] Board of Pharmacy and talked to their legal counsel and this was the recommendation they gave us at that time pursuant to the fact that there has never been any definite law or regulation passed, etc. These are recommendations by my local drug inspector who happened to come in and made the recommendation to me before we made any changes with the machine as far as packaging goes. We called the Board of Pharmacy for their ruling on it and this is the recommendation they passed on to me.

Q. Did you personally make that phone call? A. Yes, sir.

Q. And do you remember who you talked to? A. I talked to Frank Wickham, who is the executive secretary and when I explained what my query was about he transferred my call to the legal counsel in their office.

Defendant's Exhibit 63 (Premo)

Q. Do you remember his name? A. I don't recall his name.

Q. And he was with the Board of Pharmacy? A. Yes sir.

[63] Q. Of the State of Ohio? A. Yes sir.

Q. Did you ever speak to anybody at the Ohio Attorney General's Office on this matter? A. No sir.

Q. What specifically did this legal counsel tell you? A. He told me that this is — at the present time this is what some of the pharmacies that are re-packaging are doing, and he recommended if I were making a change that I would be within the guidelines right now until they make final —

MR. COBRIN: Can we note for the record the witness is pointing to which exhibits?

MR. RAUBICHECK: 13A, 13B, 14, and 15.

THE WITNESS: They are all identical.

MS. FRIEDMAN: They are not all identical.

THE WITNESS: The labeling is identical.

MS. FRIEDMAN: Not on 14.

THE WITNESS: 13A, 13B, and 15.

Q. You mentioned an inspector. To whom were you referring when you made that statement? [64] A. That would be the district pharmacy inspector of the Board of Pharmacy,

Defendant's Exhibit 63 (Premo)

representative of the Board of Pharmacy who comes in routinely.

Q. Did you speak with him after you talked to the legal counsel? A. Prior to.

Q. Prior to? A. Right.

Q. And what was the essence of your conversation with him about the labeling of your packages of cyclandelate? A. Well, at the time we were using the name — which they have all been exhausted from our inventory — we were using the name Cyclospasmol with a capital "G" to designate a generic form of Cyclospasmol, or cyclandelate, and he looked at the package and stated that we should make modifications, etc., etc. That's when we instituted the phone call, found out, and had these new tags made up.

Q. Did both the Board of Pharmacy inspector and the legal counsel indicate or state to you that it was permissible under Ohio law to use the name [65] Cyclospasmol on your packaging? A. My interpretation of the Ohio Revised Code said I may label a common name so as not to confuse the public.

Q. You say your interpretation. Did they tell you that, or — A. It's my interpretation.

Q. Do you recall the name of the inspector? A. Virgil Manley.

Q. Do you recall approximately when you spoke with the Board of Pharmacy inspector about this matter? A. It was before we moved in the new store, so it would have to be in September sometime.

Defendant's Exhibit 63 (Premo)

Q. September of 1979? A. Right.

Q. And when did you talk to the Ohio Board of Pharmacy legal counsel about this matter? A. It was shortly after we moved.

Q. And when did you move? A. October 15th.

Q. Of 1979? A. Right.

* * *

[81] Q. Mr. Prinz, with respect to Exhibits 13A, 13B, 14, and 15, did the labeling which you placed on these exhibits — was the language that you put on them influenced by the color of the capsules you put in the package? A. Yes, sir.

Q. Do you think it's desirable to have cyclandelate in the same appearance as Cyclospasmol?

MR. RAUBICHECK: Object to the question.

MR. COBRIN: You can answer the question, Mr. Prinz. A. My own personal belief is that when generics or generic equivalents are on the market for a branded name drug entity, that it does not allow for any confusion on the part of the patient when they take the medication. The basic law in the State of Ohio was passed and put together for the one sole purpose of saving money or saving dollars for prescriptions filled for patients, and in working with nursing homes we were working primarily with a geriatric patient who has taken a particular medication for [82] a period of years, he is familiar not with the medication or what it does, but with a blue capsule

Defendant's Exhibit 63 (Premo)

or orange pill with a red liquid, etc., etc. To make an abrupt change would then in the mind of the patient present some problem or might present some problem.

MR. RAUBICHECK: The Plaintiff objects to the question. The Plaintiff also objects to the testimony on the grounds of improper foundation. There has been no testimony establishing Mr. Prinz as an expert in the field of prescribing drugs or as an expert in interpreting the statutes of Ohio insofar as they pertain to dispensing prescription drugs.

Q. Mr. Prinz, how long have you been a registered pharmacist in the State of Ohio? A. Twenty-seven years.

Q. And I take it when you gave that last answer, were you answering based on your 27 years of experience in dispensing drugs? A. Yes, sir.

Q. With respect to patients who walk into your store and get cyclandelate, the generic version as distinct from [83] the Cyclospasmol, in every version is the generic cheaper or more expensive or what? A. It's always less expensive.

Q. When you stock generic drugs do you attempt to get look alikes? A. With the majority of the generic medications that we dispense going to nursing homes, the first thing I attempt to find out, if the product has been legally cleared, that it is available legally, that we are not infringing on patents, whatever, etc., etc. The next thing I look for is that we have a look alike.

Q. Have you ever received any promotional materials from Premo Pharmaceutical Laboratories? A. Not to the best of my knowledge.

Defendant's Exhibit 63 (Premo)

Q. I show you what Plaintiff has marked as Exhibit 7 and I think you have testified that one of these prescriptions was filled with Cyclospasmol. A. Yes.

Q. And were the rest filled generically? Is that right? A. Yes, sir.

Q. Can you tell us what the circumstances were such that one [84] was filled with Cyclospasmol and the remainder were filled generically? I handed the witness Exhibit 7. A. Looking at Exhibit 7, do you want me to comment on each one, or —

Q. Yes, if you would, and in fact if you could take a pencil and write "A", "B", "C", "D" on them and — A. Okay, Exhibit 7A, the prescription was written for Cyclospasmol 200 milligrams, dispense one, three times a day. We have so indicated under the prescription No. 410645, the capital "G" designating we used the generic equivalent of Cyclospasmol. The price charged was $3.75 for 50 capsules, which is the generic pricing based on the cost of medication plus we run on a fee system on filling prescriptions. It would be our normal fee plus the price.

Q. Why was that filled with cyclandelate rather than Cyclospasmol — the one you put an "A" on? A. Because we told the patient that we had the generic equivalent available, gave him the pricing on both Cyclospasmol and cyclandelate, and he made the [85] decision as to which product we were to use.

Q. Could you continue and put a "B" on the second one? A. On "B" is a prescription for Cyclospasmol 400 milligrams number 50. The order reads one morning and

Defendant's Exhibit 63 (Premo)

evening, and here again Prescription No. 409849, de
with a capital "G". The same situation took place and
time we charged $4.00 for 50 of the cyclandelate 400 mil
I can comment on this one — due to the copying I
number did not come out clear. I'll put a "C" on this
reference to this. This is one of the patients I have a pr
It's a prescription for Cyclospasmol 400 milligrams, o
times a day. This prescription was filled originally
capsules for $12.75 and the generic became available
called the physician and there is a note down in the cor
dated 9/3/75, "M.D. okays change in RX and to ref
status". At that time when we dispensed the generic we
the price from $12.75 for 120 to $5.45 for 60. The patient
a lesser amount because the doctor [86] changed the dos
original dosage was four times a day.

Q. You're referring to the one that has what l
it? A. Marked "C". Exhibit "D", a prescription was wr
Cyclospasmol 200 milligram, number 100, one tablet fo
a day for circ, which would be an abbreviation for circ
The doctor did specify in his own handwriting "DAW
meant that Ives branded cyclandelate was used. Prescrip
409936. The patent was charged $11.10 for 100 capsules.
E, prescription for Cyclospasmol 200 milligrams num
One capsule four times a day. As previously indica
patient was given the option and the pricing of both an
to take the generic equivalent. The charge was $6.00
capsules.

Q. Thank you. With respect to Exhibit 10, is t
shown to the public — this bottle? A. Per se, no.

Q. And how about Exhibit 11? A. No.

Defendant's Exhibit 63 (Premo)

[87] Q. I show you Plaintiff's Exhibit 17 and I turned to the section which has generic tablets and capsules. Do you see where there is a reference — as an example, let's go to Page 5 for cyclandelate and in caps "Generic for Cyclospasmol". Do you think it's beneficial as a pharmacist that the generic product is referenced to the Cyclospasmol product in that catalogue based on your 27 years of experience? A. Looking at Exhibit 17, Page 5, in reference to the listing of cyclandelate, it reads "cyclandelate capsules, generic for Cyclospasmol". I know that Cyclospasmol is cyclandelate. It might be beneficial for those who don't use generics if they were so inclined to purchase, it would be an easy reference as any book, any catalogue. Sears catalogue has a reference indication and I'm sure this would follow along.

Q. Does a reference such as shown in Exhibit 17 where cyclandelate is referenced to Cyclospasmol suggest to you that if you have a prescription for Cyclospasmol DAW, that it should be filled generically? [88] Q. No. Sir.

Q. In the catalogues that you receive from companies who wish to sell you products, do you generally find that the generic product is referenced to a brand name product? A. Yes — each and every one.

Q. Do you think this is beneficial? A. Saves time if you're going to check a product to see a price, availability, etc.

Q. Do you have any problem in Exhibit 17 figuring out which is the generic product and which is the brand name product? A. No.

Q. I show you Exhibit 18 which Mr. Raubicheck marked before and I notice that there are two columns. It says "Name

Defendant's Exhibit 63 (Premo)

Brand" and "Generic Brand". Do you have any trouble telling which is the name brand product and which is the generic product? A. No.

Q. Now, does Exhibit 18 suggest to you as a pharmacist practicing in the State of Ohio that if you receive [89] a prescription for Cyclospasmol DAW that it ought to be dispensed generically? A. No sir — it should be DAW — dispensed as written.

Q. I show you Exhibit 19 which was marked by Plaintiffs and ask you if you could look through it and do you have any problem looking in that exhibit and figuring out which is the brand name product and which is the generic? A. No, because they are identified at the top. Name brand and then the next column indicates the manufacturer's name and their generic brand.

Q. Does Exhibit 19 suggest to you as a registered pharmacist in the State of Ohio that if you have a prescription for Cyclospasmol DAW that it should be filled generically? A. No, sir.

Q. I show you Exhibit 20 which is the Generix Drug Catalogue. Do you have a problem in looking through that catalogue and figuring out which is the generic and which is the branded product? A. No.

[90] Q. Does that suggest to you that a prescription for Cyclospasmol DAW ought to be filled generically? A. No, sir.

Q. And finally I show you the Michigan Pharmacal catalogue Exhibit 21. Do you have any problem figuring out

Defendant's Exhibit 63 (Premo)

which is the generic and which is the branded products listed? A. No, because it so indicates "Brand Name" in heavy print and in italics it says "generic" in light print.

Q. Does that catalogue suggest to you that a prescription for Cyclospasmol DAW ought to be filled generically? A. No, sir.

Q. Have you ever seen a generic cyclandelate, the 200 milligrams, which isn't blue? A. I never have, no sir.

Q. Have you seen a generic cyclandelate 400 milligrams which isn't blue and red? A. No, sir.

Q. Do the patients who come to your store to have their prescriptions filled show a concern for the price of their products? [91] A. Most definitely.

Q. And in your opinion based on your dealings with these patients is that why a certain percentage of them want generic products? A. Yes sir.

* * *

Q. You stated before that the difference in the generic and the brand name drug is a savings to the consumer? A. Yes.

Q. Okay, as a pharmacist does it take you extra time and effort when you prescribe a generic instead of a brand name? A. When I elect the option provided under the State law to use the pharmacist's selectivity of the product, yes, [92] it does take longer because I have to price both products, I have to engage the customer in conversation and allow them to make the decision. Yes, it does take longer.

Defendant's Exhibit 63 (Premo)

Q. Do you feel the customer's satisfaction is worth the effort? A. Right. As a pharmacist working in one spot for 26 years and having continuously to tell people their prescriptions have gone up, it's a relief to say now, "I can save you three or four dollars on the prescription." I'm not the heavy anymore.

Q. And when you were referring to the catalogues, Plaintiff's Exhibits 17 through 21, you stated that no, the joint listing of generic and brand name does not suggest to you a substitution of one for the other. A. No way whatsoever.

Q. Could you explain why? A. Well, looking at Exhibit 9, the bottle is labeled cyclandelate underneath in half-size print, which is the chemical name of the product so branded by Ives as Cyclospasmol, its branded name. And, as a [93] practicing pharmacist I am aware that all Cyclospasmol is cyclandelate and all cyclandelate is Cyclospasmol.

* * *

GRAND JURY INDICTMENTS JUDICIALLY NOTICED BY COURT OF APPEALS

Grand Jury Indictments

SUPREME COURT OF THE STATE OF NEW YORK
BRONX COUNTY

INDICTMENT NUMBER 1056/80

THE PEOPLE OF THE STATE OF NEW YORK

-AGAINST-

MELROSE PHARMACY, INC.

Defendant.

COUNTS

OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE	(5 COUNTS)
DEVIATING FROM THE TERMS OF A PRESCRIPTION	(10 COUNTS)
MISBRANDING A DRUG	(2 COUNTS)
ATTEMPTED PETIT LARCENY	(6 COUNTS)

TRUE BILL

s/ Frank Barell
FOREMAN, GRAND JURY

S/ Charles J. HYNES
DEPUTY ATTORNEY GENERAL
STATE OF NEW YORK
270 Broadway
New York, New York 10007

COUNT 1 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Melrose Pharmacy, Inc. a domestic corporation in the State of New York, did, in the County of Bronx, on or about December 19, 1979, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false

statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 2 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx on or about January 3, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

Grand Jury Indictments

COUNT 3 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about January 4, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 4 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST

DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Melrose Pharmacy, Inc. a domestic corporation in the State of New York, did, in the County of Bronx, on or about January 14, 1980 commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendnat, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 5 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of

Bronx, on or about January 21, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 6 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about October 16, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the

defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Pedro Ortiz an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 7 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about October 25, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

Grand Jury Indictments

COUNT 8 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law); committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about November 2, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 9 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc. a domestic corporation organized in the State of New York, did, in the

County of Bronx, on or about December 13, 1979 co
crime of DEVIATING FROM THE TERMS
PRESCRIPTION, to wit: an agent of the defenda
acting within the scope of his employment and in beh
defendant, in the course of putting up a drug and
making up a prescription and filling an order for d
medicine, did deviate from the terms of the prescripti
and demand for ELAVIL by substituting and disp
different article and drug for and in lieu of the article
prescribed, and otherwise deviated from the term
prescription order and demand by substituting one
another, to wit, the defendant dispensed to one Hector
article and drug contrary to the terms of the prescripti
and demand for ELAVIL.

COUNT 10 THE GRAND JURY OF THE COU
BRONX by this indictment, accuse the d
of the crime of DEVIATING FRO
TERMS OF A PRESCRIPTION (in vio
Section 6816 of the Education Law), com
follows:

The defendant, Melrose Pharmacy, Inc., a
corporation organized in the State of New York, di
County of Bronx on or about December 19, 1979 co
crime of DEVIATING FROM THE TERMS
PRESCRIPTION, to wit: an agent of the defenda
acting within the scope of his employment and in beh
defendant, in the course of putting up a drug and
making up a prescription and filling an order for d
medicine, did deviate from the terms of the prescripti
and demand for ELAVIL by substituting and disp
different article and drug for and in lieu of the article

prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 11 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about December 27, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 12 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE

TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 3, 1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 13 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 4, 1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while

acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 14 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 14, 1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio

Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 15 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 21, 1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 16 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

Grand Jury Indictments

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about November 2, 1979 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container DIURIL when in truth and fact its contents were not DIURIL.

COUNT 17 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6311(10) of the Education Law) committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about January 14, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and fact its contents were not CYCLOSPASMOL.

COUNT 18 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about November 2, 1979, with the intent

to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that DIURIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 19 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 19, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

Grand Jury Indictments

COUNT 20 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows;

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 3, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 21 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 4, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to

be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 22 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 14, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit; an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 23 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

Grand Jury Indictments

The defendant, Melrose Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 21, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF KINGS

INDICTMENT NUMBER
1236/80
153/413B

THE PEOPLE OF THE STATE OF NEW YORK,

-against-

SOEL MELERO,

Defendant.

Grand Jury Indictments

COUNTS

DEVIATING FROM THE TERMS OF A PRESCRIPTION (2 COUNTS)

MISBRANDING A DRUG (2 COUNTS)

TRUE BILL

s/ Laura Barbuzza
FORELADY, GRAND JURY

s/ Charles J. Hynes
CHARLES J. HYNES
DEPUTY ATTORNEY GENERAL
STATE OF NEW YORK
270 Broadway
New York, New York 10007

COUNT 1 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Soel Melero on or about December 7, 1980, in the County of Kings in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for an in lieu of the article

and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Joseph Gomez an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 2 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Soel Melero on or about February 15, 1980, in the County of Kings in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Joseph Gomez an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 3 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Soel Melero on or about February 7, 1979, in the County of Kings did misbrand a drug by falsely labeling

its container CYCLOSPASMOL when in truth and in fact the contents were not CYCLOSPASMOL.

COUNT 4 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Soel Melero on or about February 15, 1980, in the County of Kings did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and in fact the contents were not CYCLOSPASMOL.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF KINGS

INDICTMENT NUMBER

1235/80
153/413A

THE PEOPLE OF THE STATE OF NEW YORK

-against-

PUEBLOS PHARMACY, INC.,

Defendant.

COUNTS

OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE	(4 COUNTS)
DEVIATING FROM THE TERMS OF A PRESCRIPTION	(5 COUNTS)
MISBRANDING A DRUG	(2 COUNTS)
ATTEMPTED PETIT LARCENY	(4 COUNTS)

TRUE BILL

s/ Laura Barbuzza
FORELADY, GRAND JURY

s/ Charles J. Hynes
CHARLES J. HYNES
DEPUTY ATTORNEY GENERAL
STATE OF NEW YORK
270 Broadway
New York, New York 10007

COUNT 1 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc. a domestic corporation in the State of New York, did, in the County of

Kings on or about October 25, 1979, commit the OFFERING A FALSE INSTRUMENT FOR FILING FIRST DEGREE, to wit: a high managerial age defendant, while acting within the scope of his employ in behalf of the defendant, knowing that a written instr wit, a New York State Medical Assistance (Title XIX) Pharmacy Claim Form contained false information statements, and with the intent to defraud the Stat York, did offer and present said written instrument t office, to wit, the New York State Department Services, with the knowledge and belief that sai instrument would be filed with, registered, recorde otherwise become a part of the records of said public o New York State Medical Assistance (Title XIX) Pharmacy Claim Form contained false information statements, in that it was claimed thereon that DI dispensed and furnished to Joseph Gomez, whereas, in in fact, as the defendant well knew, a different a dispensed and furnished.

COUNT 2 THE GRAND JURY OF THE COU KINGS by this indictment, accuse the of the crime of OFFERING A INSTRUMENT FOR FILING IN TH DEGREE (in violation of Section 175 Penal Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc. a corporation in the State of New York, did, in the Kings on or about November 21, 1979, commit th OFFERING A FALSE INSTRUMENT FOR FILIN FIRST DEGREE, to wit: a high managerial ag defendant, while acting within the scope of his emplo

in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that DIURIL was dispensed and furnished to Joseph Gomez, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 3 THE GRAND JURY OF THE COUNTY OF KINGS, by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc. a domestic corporation in the State of New York, did, in the County of Kings on or about November 28, 1979, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New

York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that DIURIL was dispensed and furnished to Joseph Gomez, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 4 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc. a domestic corporation in the State of New York, did, in the County of Kings on or about February 7, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and

otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Joseph Gomez, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 5 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about October 25, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Joseph Gomez an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

Grand Jury Indictments

COUNT 6 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about November 21, 1970 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Joseph Gomez an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 7 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

Grand Jury Indictments

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about November 28, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Joseph Gomez an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 8 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about February 7, 1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and

dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Joseph Gomez an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 9 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about February15,1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Joseph Gomez an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 10 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of

Grand Jury Indictments

MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Kings on or about February 15, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and fact its contents were not CYCLOSPASMOL.

COUNT 11 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Kings on or about February 7, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and fact its contents were not CYCLOSPASMOL.

COUNT 12 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

Grand Jury Indictments

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about November 28, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that DIURIL was dispensed and furnished to Joseph Gomez with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 13 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about February 7, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Joseph Gomez with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

Grand Jury Indictments

COUNT 14 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about November 21, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that DIURIL was dispensed and furnished to Joseph Gomez with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 15 THE GRAND JURY OF THE COUNTY OF KINGS by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, Pueblos Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Kings on or about October 25, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to

be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that DIURIL was dispensed and furnished to Joseph Gomez with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF BRONX

INDICTMENT NUMBER 1062/80

THE PEOPLE OF THE STATE OF NEW YORK,

-against-

BENJAMIN BERNSTEIN,

Defendant.

COUNTS

OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE	(10 COUNTS)
DEVIATING FROM THE TERMS OF A PRESCRIPTION	(16 COUNTS)
MISBRANDING A DRUG	(9 COUNTS)
ATTEMPTED PETIT LARCENY	(10 COUNTS)

TRUE BILL

s/ Frank Burrelli
FOREMAN, GRAND JURY

S/ Charles J. Hynes
CHARLES J. HYNES
DEPUTY ATTORNEY GENERAL
STATE OF NEW YORK
270 Broadway
New York, NY 10007

COUNT 1 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 13, 1979, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

Grand Jury Indictments

COUNT 2 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 19, 1979, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 3 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 20, 1979, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title

XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that KENACORT as dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 4 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 27, 1979, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false

information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 5 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 27, 1979, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that KENACORT was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 6 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST

DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 3, 1980, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 7 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 11, 1980, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written

instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 8 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 14, 1980, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

Grand Jury Indictments

COUNT 9 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 21, 1980, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 10 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 29, 1980, in the County of Bronx knowing that a written instrument, to wit, a New York State Medical Assistance (Title

XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 11 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about October 5, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Pedro Ortiz an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

Grand Jury Indictments

COUNT 12 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about October 12, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Pedro Ortiz an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 13 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about October 25, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the

prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 14 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about November 2, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 15 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 10, 1979, in the County of Bronx in the course of putting up a

drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for KENACORT by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for KENACORT.

COUNT 16 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 13, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 17 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant

of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 19, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 18 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 20, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for KENACORT by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant

dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for KENACORT.

COUNT 19 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 27, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for KENACORT by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for KENACORT.

COUNT 20 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about December 27, 1979, in the County of Bronx in the course of putting up a

drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 21 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 3, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 22 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of

Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 11, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 23 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 14, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

Grand Jury Indictments

COUNT 24 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 17, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 25 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 21, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for an in

lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 26 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, Benjamin Bernstein, on or about January 29, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 27 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

Grand Jury Indictments

The defendant, Benjamin Bernstein, on or about December 13, 1979, in the County of Bronx did misbrand a drug by falsely labeling its container ELAVIL when in truth and in fact the contents were not ELAVIL.

COUNT 28 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Benjamin Bernstein, on or about December 19, 1979, in the County of Bronx did misbrand a drug by falsely labeling its container ELAVIL when in truth and in fact the contents were not ELAVIL.

COUNT 29 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Benjamin Bernstein, on or about December 27, 1979, in the County of Bronx did misbrand a drug by falsely labeling its container ELAVIL when in truth and in fact the contents were not ELAVIL.

COUNT 30 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

Grand Jury Indictments

The defendant, Benjamin Bernstein, on or about January 3, 1980, in the County of Bronx did misbrand a drug by falsely labeling its container ELAVIL when in truth and in fact the contents were not ELAVIL.

COUNT 31 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Benjamin Bernstein, on or about January 11, 1980, in the County of Bronx did misbrand a drug by falsely labeling its container ELAVIL when in truth and in fact the contents were not ELAVIL.

COUNT 32 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Benjamin Bernstein, on or about January 14, 1980, in the County of Bronx did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and in fact the contents were not CYCLOSPASMOL.

COUNT 33 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

Grand Jury Indictments

The defendant, Benjamin Bernstein, on or about January 17, 1980, in the County of Bronx did misbrand a drug by falsely labeling its container ELAVIL when in truth and in fact the contents were not ELAVIL.

COUNT 34 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Benjamin Bernstein, on or about January 21, 1980, in the County of Bronx did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and in fact the contents were not CYCLOSPASMOL.

COUNT 35 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, Benjamin Bernstein, on or about January 29, 1980, in the County of Bronx did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and in fact the contents were not CYCLOSPASMOL.

COUNT 36 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

Grand Jury Indictments

The defendant Benjamin Bernstein, on or about December 13, 1979, in the County of Bronx, with intent to commit the crime of Petit Larceny, engaged in conduct which tended to effect the commission of said crime, in that the defendant did attempt to steal a sum of money from the State of New York by submitting New York State Medical Assistance (Title XIX) Program Pharmacy Claim Forms in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres, intending that the New York State Department of Social Services, in reliance thereon, would pay him a sum of money to which he was not entitled.

COUNT 37 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant Benjamin Bernstein, on or about December 19, 1979, in the County of Bronx, with intent to commit the crime of Petit Larceny, engaged in conduct which tended to effect the commission of said crime, in that the defendant did attempt to steal a sum of money from the State of New York by submitting New York State Medical Assistance (Title XIX) Program Pharmacy Claim Forms in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres, intending that the New York State Department of Social Services, in reliance thereon, would pay him a sum of money to which he was not entitled.

COUNTS 38 THROUGH 45
UNINTELLIGIBLE IN ORIGINAL.

Grand Jury Indictments

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF BRONX

INDICTMENT NUMBER 1057/80

PEOPLE OF THE STATE OF NEW YORK

-against-

JAMES DETURA

Defendant

COUNTS

OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE	(4 COUNTS)
DEVIATING FROM THE TERMS OF A PRESCRIPTION	(4 COUNTS)
ATTEMPTED PETIT LARCENY	(4 COUNTS)

TRUE BILL

s/ Frank Burelli
FOREMAN, GRAND JURY

s/ Charles J. Hynes
CHARLES J. HYNES
DEPUTY ATTORNEY GENERAL
STATE OF NEW YORK
270 Broadway
New York, New York 10007

Grand Jury Indictments

COUNT 1 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, James Detura, on or about December 19, 1979, in the County of Bronx, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 2 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, James Detura, on or about January 3, 1980, in the County of Bronx, knowing that a written

instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 3 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, James Detura, on or about January 4, 1980, in the County of Bronx, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program

Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 4 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, James Detura, on or about January 21,1980, in the County of Bronx, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 5 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE

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TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, James Detura, on or about December 19, 1979, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 6 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, James Detura, on or about January 3, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 7 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, James Detura, on or about January 4, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 8 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, James Detura, on or about January 21, 1980, in the County of Bronx in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of a prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for an in lieu of the article and drug prescribed, and otherwise deviated from the terms of

the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 9 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, James Detura, on or about December 19, 1979 in the County of Bronx, with intent to commit the crime of Petit Larceny, engaged in conduct which tended to effect the commission of said crime, in that the defendant did attempt to steal a sum of money from the State of New York by submitting New York State Medical Assistance (Title XIX) Program Pharmacy Claim Forms in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres intending that the New York State Department of Social Services, in reliance thereon, would pay him a sum of money to which he was not entitled.

COUNT 10 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, James Detura, on or about January 3, 1980, in the County of Bronx, with intent to commit the crime of Petit Larceny, engaged in conduct which tended to effect the commission of said crime, in that the defendant did attempt to

steal a sum of money from the State of New York by submitting New York State Medical Assistance (Title XIX) Program Pharmacy Claim Forms in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres intending that the New York State Department of Social Services, in reliance thereon, would pay him a sum of money to which he was not entitled.

COUNT 11 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, James Detura, on or about January 4, 1980, in the County of Bronx, with intent to commit the crime of Petit Larceny, engaged in conduct which tended to effect the commission of said crime, in that the defendant did attempt to steal a sum of money from the State of New York by submitting New York State Medical Assistance (Title XIX) Program Pharmacy Claim Forms in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada intending that the New York State Department of Social Services, in reliance thereon, would pay him a sum of money to which he was not entitled.

COUNT 12 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, James Detura, on or about January 21, 1980, in the County of Bronx, with intent to commit the crime of Petit

Larceny, engaged in conduct which tended to effect the commission of said crime, in that the defendant did attempt to steal a sum of money from the State of New York by submitting New York State Medical Assistance (Title XIX) Program Pharmacy Claim Forms in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada intending that the New York State Department of Social Services, in reliance thereon, would pay him a sum of money to which he was not entitled.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF BRONX

INDICTMENT NUMBER 1061/80

THE PEOPLE OF THE STATE OF NEW YORK

-against-

B & B PHARMACY, INC.,

Defendant.

COUNTS

OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE	(10 COUNTS)
DEVIATING FROM THE TERMS OF A PRESCRIPTION	(16 COUNTS)

MISBRANDING A DRUG (9 COUNTS)

ATTEMPTED PETIT LARCENY (11 COUNTS)

A TRUE BILL

s/ Frank Burelli
Foreman, Grand Jury

s/ Charles J. Hynes
Deputy Attorney General
State of New York
270 Broadway
New York, New York 10007

COUNT 1 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about December 13, 1979, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New

York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 2 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about December 19, 1979, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and

otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 3 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about December 20, 1979, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that KENACORT was dispensed and furnished to Emilio Estrada, whereas, in truth

and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 4 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about December 27, 1979, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 5 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant

of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about December 27, 1979, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that KENACORT was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 6 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

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The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about January 3, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 7 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about January 11, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE

FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that ELAVIL was dispensed and furnished to Hector Torres, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 8 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about January 14, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program

Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistnace (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 8 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about January 21, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social

Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistnace (Title XIX) Program Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 10 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE (in violation of Section 175.35 of the Penal Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation in the State of New York, did, in the County of Bronx, on or about January 29, 1980, commit the crime of OFFERING A FALSE INSTRUMENT FOR FILING IN THE FIRST DEGREE, to wit: a high managerial agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, knowing that a written instrument, to wit, a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form contained false information and false statements, and with the intent to defraud the State of New York, did offer and present said written instrument to a public office, to wit, the New York State Department of Social Services, with the knowledge and belief that said written instrument would be filed with, registered, recorded in and otherwise become a part of the records of said public office. Said New York State Medical Assistnace (Title XIX) Program

Pharmacy Claim Form contained false information and false statements, in that it was claimed thereon that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada, whereas, in truth and in fact, as the defendant well knew, a different article was dispensed and furnished.

COUNT 11 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about October 5, 1979, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Pedro Ortiz an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 12 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE

TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about October 12, 1979, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Pedro Ortiz an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 13 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about October 25, 1979, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while

acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 14 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about November 2, 1979, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for DIURIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres,

an article and drug contrary to the terms of the prescription, order and demand for DIURIL.

COUNT 15 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 10, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for KENACORT by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for KENACORT.

COUNT 16 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

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The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 13, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 17 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as foltows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 19, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order

and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 18 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 20, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for KENACORT by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for KENACORT.

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COUNT 19 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 27, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for KENACORT by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for KENACORT.

COUNT 20 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the

County of Bronx on or about December 27, 1979 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 21 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 3, 1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug

prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 22 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 11, 1980 commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 23 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE

TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 17, 1980, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 24 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 17, 1980, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while

acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for ELAVIL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Hector Torres an article and drug contrary to the terms of the prescription, order and demand for ELAVIL.

COUNT 25 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 21, 1980, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio

Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 26 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment, accuse the defendant of the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION (in violation of Section 6816 of the Education Law), committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 29, 1980, commit the crime of DEVIATING FROM THE TERMS OF A PRESCRIPTION, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, in the course of putting up a drug and medicine, making up a prescription and filling an order for drugs and medicine, did deviate from the terms of the prescription, order and demand for CYCLOSPASMOL by substituting and dispensing a different article and drug for and in lieu of the article and drug prescribed, and otherwise deviated from the terms of the prescription, order and demand by substituting one drug for another, to wit, the defendant dispensed to one Emilio Estrada an article and drug contrary to the terms of the prescription, order and demand for CYCLOSPASMOL.

COUNT 27 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about December 13, 1979 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container ELAVIL when in truth and fact its contents were not ELAVIL.

COUNT 28 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about December 19, 1979 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container ELAVIL when in truth and fact its contents were not ELAVIL.

COUNT 29 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about January 3, 1980 commit the

crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container ELAVIL when in truth and fact its contents were not ELAVIL.

COUNT 30 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about January 11, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container ELAVIL when in truth and fact its contents were not ELAVIL.

COUNT 31 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about January 14, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely

labeling its container CYCLOSPASMOL when in truth and fact its contents were not CYCLOSPASMOL.

COUNT 32 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about January 17, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container ELAVIL when in truth and fact its contents were not ELAVIL.

COUNT 33 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about January 21, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and fact its contents were not CYCLOSPASMOL.

Grand Jury Indictments

COUNT 34 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about January 29, 1980 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container CYCLOSPASMOL when in truth and fact its contents were not CYCLOSPASMOL.

COUNT 35 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of MISBRANDING A DRUG (in violation of §6811(10) of the Education Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York did, in the County of Bronx on or about December 27, 1979 commit the crime of MISBRANDING A DRUG, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, did misbrand a drug by falsely labeling its container ELAVIL when in truth and fact its contents were not ELAVIL.

COUNT 36 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in

violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 13, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 37 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 19, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to

Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 38 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 20, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that KENACORT was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 39 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 27, 1979, with the

intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 40 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about December 27, 1979, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that KENACORT was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 41 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant

of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx on or about January 3, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 42 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 11, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and

falsely claimed that ELAVIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 43 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 14, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 44 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

Grand Jury Indictments

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 17, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that ELAVIL was dispensed and furnished to Hector Torres with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 45 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 21, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

COUNT 46 THE GRAND JURY OF THE COUNTY OF BRONX by this indictment accuse the defendant of ATTEMPTED PETIT LARCENY (in violation of Sections 110.00 and 155.25 of the Penal Law) committed as follows:

The defendant, B & B Pharmacy, Inc., a domestic corporation organized in the State of New York, did, in the County of Bronx, on or about January 29, 1980, with the intent to commit the crime of PETIT LARCENY, engage in conduct which tended to effect the commission of said crime, to wit: an agent of the defendant, while acting within the scope of his employment and in behalf of the defendant, filed and caused to be filed a New York State Medical Assistance (Title XIX) Program Pharmacy Claim Form in which he knowingly and falsely claimed that CYCLOSPASMOL was dispensed and furnished to Emilio Estrada with the intent that the New York State Department of Social Services, through its authorized fiscal agent, pay a sum of money to the defendant in reliance thereon.

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ALEXANDER L. STEVAS,
CLERK

No. 80-2182
No. 81-11

In The

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

DARBY DRUG CO., INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

JOINT APPENDIX

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Petition for *Certiorari* Filed June 24, 1981
***Certiorari* Granted October 13, 1981**

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8*	Ives Package and Bottle of 200 mg. CYCLOSPASMOL Capsules, Physician Sample (Photograph Copy)	571a
18*	U.S. Patent #2,707,193	572a
19B*	Title Page and Excerpt (p. 153) on CYCLOSPASMOL from Book entitled, "Prescription Drugs," by the Editors of CONSUMER GUIDE	573a
26*	One Individually Wrapped 400 mg. Capsule Labeled in Part "CYCLANDELATE 400 mg. CYCLOSPASMOL — CALVINSG⁹" (Photograph Copy)	576a
27*	One Individually Wrapped 400 mg. Capsule Labeled in Part "CYCLOSPASMOL (G) 400 mg." from Calvin's Drug Store (Photograph Copy)	576a
28*	One Bottle and Blue/Red Capsule from Medical Arts Pharmacy, Syracuse, NY, Labeled in Part "CYCLOSPASMAL" [sic]" (Photograph Copy)	577a

* Exhibits which have an asterisk after their number appear in the oversized exhibit volume.

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30*	One Bottle and Blue/Red Capsule from Medical Arts Pharmacy, Syracuse, NY, Labeled in Part "CYCLOSPASMOL" (Photograph Copy)	579a
33*	One Bottle and Blue/Red Capsule from NRTA/AARP Pennsylvania Retired Persons Pharmacy, Warminster, PA, Labeled in Part "CYCLOSPASMOL 400 mg. (GENERIC)" (Photograph Copy)	580a
34*	One Bottle and Blue/Red Capsule from Medical Arts Pharmacy, Syracuse, NY, Labeled in Part "CYCLOSPASMOL" (Photograph Copy)	581a
35*	One Bottle and Blue/Red Capsule from Medical Arts Pharmacy, Syracuse, NY, Labeled in Part "CYCLOSPASMOL" (Photograph Copy)	582a
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65*	Specimen of Patient Questionnaire with Accompanying Name Cards	668a
66*	Administrative Instructions — Doctor Study	682a
67*	Interviewing Instructions — Doctor Study with Addendum	686a
74	A Study of Recognition of Drugs by Prescribers and Users (Jan. 1980)	319a
75	Update and Summary Analysis of Exh. 74	347a
79	Replication Sample of Patients (Supplemental Analysis)	352a
82000*	One Bottle Labeled in Part "Generic Cyclospasmol 400 mg. 539571 Inwood" (Photograph Copy) with Accompanying Shopping Report, Receipt, and Prescription	691a

Plaintiff's Exhibit No.	Description	Page
82S*	One Bottle Labeled in Part "Generic Cyclospasmol" (Photograph Copy) with Accompanying Shopping Report, Receipt, and Prescription	695a
82E*	One Bottle Labeled in Part "Cyclospasmol 400 generic" (Photograph Copy) with Accompanying Shopping Report, Receipt, and Prescription	699a
82SSS*	One Bottle Labeled in Part "Cyclospasmol Generic 200" (Photograph Copy) with Accompanying Shopping Report, Receipt, and Prescription	703a
82TTT*	One Bottle Labeled in Part "Cyclospasmol 400 (GEN) (Spencer Mead)" (Photograph Copy) with Accompanying Shopping Report, Receipt, and Prescription	707a
82BB*	One Bottle Labeled in Part "Cyclospasmol 400 mg. (Rugby)" (Photograph Copy) with Accompanying Shopping Report, Receipt, and Prescription	711a
82A*	One Bottle Labeled in Part "Hylan: Cyclospasmol" (Photograph Copy) with Accompanying Shopping Report, Receipt, and Prescription	715a

Plaintiff's Exhibit No.	Description	Page
82T*	One Bottle Labeled in Part "Cyclospasmol 200 mg." (Photographic Copy) with Accompanying Shopping Report, Receipt, and Prescription	719a
82HHH*	One Bottle Labeled in Part "Cyclospasmol 400 mg." (Photographic Copy) with Accompanying Shopping Report, Receipt, and Prescription	723a
82DDD*	One Bottle Labeled in Part "Cyclospasmol 400" (Xerox Copy — Original Bottle Lost by Court of Appeals) with Accompanying Shopping Report, Receipt, and Prescription	726a
83	Study of Prescription Filling and Labeling by Pharmacists in New York State	354a
90*	One Bottle and Capsule of CYDEL 200 mg. cyclandelate, W.E. Hauck, Inc. (Photographic Copy)	729a
92*	Excerpt from October 1978 Georgia Medical Assistance Drug List	730a
95*	One Bottle from Sentry Drugs, Southfield, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	732a

Plaintiff's Exhibit No.	Description	Page
96*	One Bottle from Merrill Pharmacy, Detroit, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	736a
97*	One Bottle from Sentry Drugs, Taylor, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	740a
98*	One Bottle from Sentry Drugs, Southfield, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	744a
99*	One Bottle from Civic Drug Center, Dearborn, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	748a
100*	One Bottle from Pickwick Pharmacy, Philadelphia, PA (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	752a
101*	One Bottle from Carlysle Pharmacy, Dearborn, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	756a

Plaintiff's Exhibit No.	Description	Page
102*	One Bottle from Sentry Drugs, Taylor, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	760a
103*	Two Bottles from Lowitt Labs, Rockaway Beach, NY (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	764a
104*	One Bottle from Carlysle Pharmacy, Dearborn, MI (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	770a
105*	One Bottle (Empty) from Tylertown Drug Store, Tylertown, Miss. (Photographic Reproduction) with Accompanying Prescription, Receipt and Shopping Report	774a
106*	One Bottle from Pickwick Pharmacy, Philadelphia, PA (Photographic Reproduction) with Accompanying Prescription and Shopping Report Only	778a
107*	One Bottle from Pickwick Pharmacy, Philadelphia, PA (Photographic Reproduction) with Accompanying Shopping Report Only	781a

Plaintiff's Exhibit No.	Description	Page
112*	Trademark Registration for CYCLOSPASMOL	783a
123	Remarks of Dr. Edward Stempel, 1960	362a
130A*	Chart of Colors of Various Drug Products	784a
138	Excerpts from Report of Attorney General Abrams and Consumer Affairs Commissioner Ratner on New York Generic Drug Substitution Law, Mar. 13, 1979	368a
142	Stipulation dated Feb. 28, 1980, re: Results of "Chung Shopping"	375a
143	Joint Designated Excerpts of Deposition Testimony of Premo by Seymour Blackman, May 4, 1978	383a
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Defendant's Exhibit No.	Description	Page
Inwood 6*	Excerpts from Publication of New York State Assembly's Office of Legislative Council entitled, "Are Generics Safe?", June 23-24, 1978	795a
Inwood 8*	Bottle and Capsule of Inwood Cyclandelate	831a
Inwood 9*	Capsules, 200 mg. and 400 mg. (Photographic Reproduction)	832a
Inwood 11*	State of New Jersey Purchase Bureau Quotation Request 1976-1977	833a
Inwood 12	List of Companies Marketing Cyclandelate products	444a
Premo 4*	Chart of National Brand Drugs and Generic Drugs Having Identical Appearances	839a
Premo 5*	Key to Chart (Premo Exh. 4)	840a
Premo 22*	Premo Product List, Dec. 1979	850a
Premo 63	Joint Designated Excerpts of Deposition Testimony of Rudolph F. Prinz, Jan. 14, 1980	448a

PLAINTIFF'S EXHIBIT 7

PLAINTIFF'S EXHIBIT 8

PLAINTIFF'S EXHIBIT 18

United States Patent Office

2,707,193

Patented Apr. 26, 1955

1

2,707,193

3,3,5-TRIMETHYL CYCLOHEXANOL-1 MANDELATE

Wijbe Thomas Nauta, Amsterdam, Netherlands, assignor to N. V. Koninklijke Pharmaceutische Fabrieken Voorheen Brocades-Stheeman & Pharmacia, Amsterdam, Netherlands, a company of the Netherlands

No Drawing. Application March 8, 1954, Serial No. 414,881

Claims priority, application Netherlands June 7, 1949

1 Claim. (Cl. 260—473)

This application is a continuation-in-part of my U. S. application Ser. No. 166,295, filed June 5, 1950, now abandoned.

Papaverine, i. e. 1-(3',4'-dimethoxybenzyl) 6.7-dimethoxy iso-quinoline, has been in use for a considerable time as a spasmolytic. A great many attempts have been made to find other spasmolytics; a summary was published by Blicke in Annual Review of Biochemistry, 13, 549–574 (1944). From this it is clear that besides amines and amides the substances attracting special attention were esters, among them esters of di-substituted acetic acids. These esters invariably contain basic nitrogen in the alcohol component. It has also been described in the literature that the piperidino-ethanol ester of di-n-butyl acetic acid is an excellent spasmolytic.

It has now been found that the 3.3.5-trimethylcyclohexanol-1 ester of mandelic acid exhibits a spasmolytic activity which is significantly surpassing that of papaverine. A great advantage consists further in that the toxicity of the said compound is small as compared with that of papaverine. Thus the LD_{50} for papaverine is 150 mg. and that of the 3.3.5-trimethylcyclohexanol-1 ester of mandelic acid about 4000 mg. both per kg. mouse and administered subcutaneously.

2

The ester described above is a novel compound.

It appeared to make little difference whether the laevo- or dextro-rotatory form of mandelic acid was used or dl-mandelic acid.

Several esters of mandelic acid were already known per se, they are the methyl, ethyl, propyl, iso-butyl, 2-methyl, butyl, n-hexyl, benzyl, menthyl and bornyl esters. I had these esters tested and found that as to their spasmolytic activity they are significantly inferior to that of the 3.3.5-trimethylcyclohexanol-1 ester, as follows from the table below:

Alcohol component	Mandelic acid	B. P. or M. P. of the ester	Antagonistic to spasms provoked in the isolated Guinea pig intestine by acetyl choline; calculated per gramamol
3.3.5-trimethylcyclohexanol-1.	dl	50–53° C.; 192–194° C./14 mm. (lower melting form). 63–66° C.; 154–155° C./1 mm. (higher melting form).	200
methanol	dl	57° C.; 137° C./16 mm.	0.3
ethanol	dl	33–34° C.; 138–141° C./14 mm.	0.7
propanol-1	dl	150° C./21 mm.	2.4
butanol-2	dl	141–142° C./12 mm.	4.6
2-methylbutanol-1	dl	165° C./20 mm.	25
benzylalcohol	dl	90–91° C.	22
1-menthyl-alcohol	dl	81–82° C.	<10
1-bornyl-alcohol	dl	75° C.	(1)
papaverine	dl		37

[1] Intestine damaged by the ester; this ester is not so much a spasmolytic, but more a paralysing drug, so that it cannot be used in practice as a spasmolytic. Accordingly, this measurement of its spasmolytic activity is not accurate; at all events it is considerably less than that of the 3.3.5-trimethylcyclohexanol-1 ester.

The activity of the 3.3.5-trimethyl cyclohexanol-1 ester has been put at 100.

The following is an example of the production of the ester claimed by means of esterification:

50 g. of dl-mandelic acid are heated for 6 hours at approximately 100° C. with 50 g. of 3.3.5-trimethyl cyclohexanol (mixture of cis- and trans-isomer), while passing dry hydrochloric acid gas through the mixture. The reaction product is subsequently poured out into water. After neutralization with potassium bicarbonate the ester is extracted with ether. The ether extract is dried with sodium sulphate, the ether is distilled off and the residue is distilled in vacuo. The fraction, which has a boiling point of 192–194° C. at 14 mm., consists of the 3.3.5-tri-methylcyclohexyl ester of mandelic acid, which is obtained in a yield of about 70%.

The liquid solidifies to a colourless solid substance having a melting point of 50–53° C.

What I claim is:

The 3.3.5-trimethylcyclohexanol-1 ester of mandelic acid.

No references cited.

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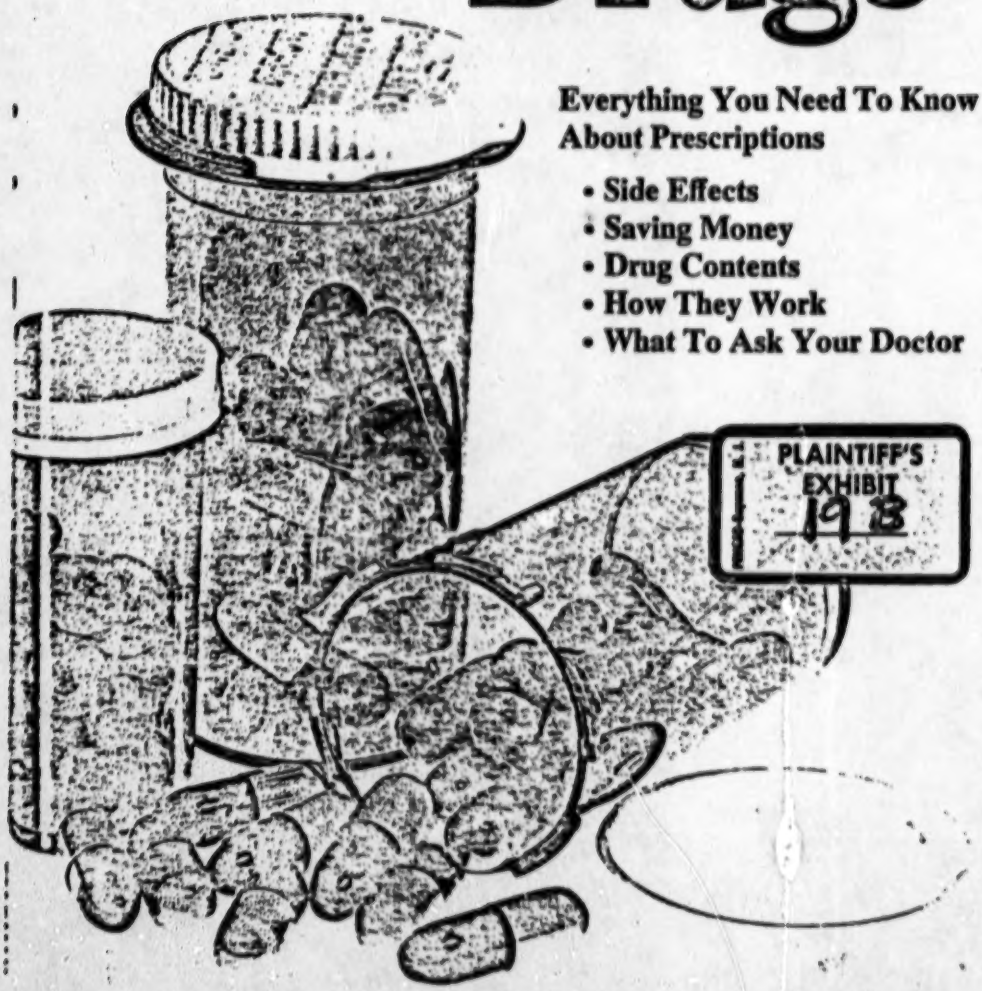
PLAINTIFF'S EXHIBIT 19B

By The Editors Of Consumer Guide®

Prescription Drugs

MARBORO 199 $2.95



Everything You Need To Know About Prescriptions

- Side Effects
- Saving Money
- Drug Contents
- How They Work
- What To Ask Your Doctor

PLAINTIFF'S EXHIBIT 19B

Plaintiff's Exhibit 19B

Prescription Drugs

by the Editors of CONSUMER GUIDE®
with Thomas A. Gossel, R.Ph., Ph.D.
and Donald W. Stansloski, R.Ph., Ph.D.

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Plaintiff's Exhibit 19B

barbiturates, chloral hydrate, chloramphenical, cholestyramine, clofibrate, dextrothyroxine, diazoxide, disulfiram, ethacrynic acid, ethchlorvynol, glucagon, glutethimide, griseofulvin, Indocin, mefenamic acid, neomycin, oral antidiabetics, oral contraceptives, oxyphenbutazone, phenylbutazone, phenytoin, quinidine, rifampin, salicylates, steroids, thyroid, triclofos, tricyclic antidepressants

Comments: Coumadin interacts with many other drugs; do not start or stop taking another medication, including aspirin, without checking with your doctor.

If clots fail to form over cuts and bruises or if purple spots appear under bruised skin, call your doctor immediately.

CYCLANFOR® (Forest Laboratories, Inc.), see Cyclospasmol®.

CYCLOSPASMOL®

Manufacturer: Ives Laboratories Inc.
Generic Name: cyclandelate
Generic Equivalents: Cyclanfor® (Forest Laboratories, Inc.); Cydel® (W.E. Hauck, Inc.)
Dosage Forms: Cyclospasmol capsules: 200 mg (blue), 400 mg (blue/red); tablets: 100 mg (orange)
Drug Category: Vasodilator
Use: Dilation of blood vessels
Minor Side Effects: Flushing, headache, stomach distress
Major Side Effects: Palpitations, weakness
Contraindications: Except during the first trimester of pregnancy, there are no documented contraindications to this drug.
Warnings and Precautions: Glaucoma, hardening of the arteries, heart disease
Interacts With: No significant drug interactions
Comments: While Cyclospasmol dilates blood vessels, a government panel of experts has determined that the drug is only "possibly" effective in the treatment of hardening of the arteries, leg cramps, and in the prevention of stroke.

While taking Cyclospasmol, do not take any nonprescription item for cough, cold, or sinus problems without first checking with your doctor.

Stomach distress is usually mild and can be avoided by taking the drug with food or an antacid.

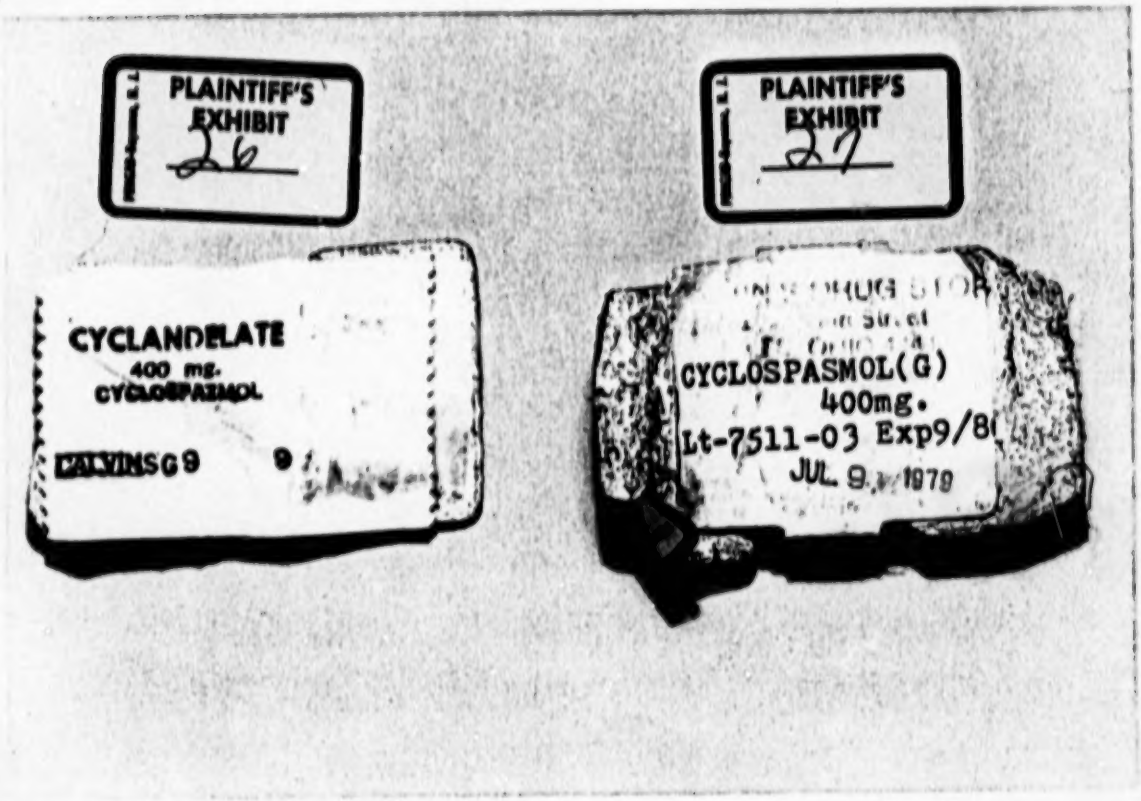
Mild side effects (e.g., nasal stuffiness) are most noticeable during the first two weeks of therapy and become less bothersome after this period.

Generic brands of Cyclospasmol are available and vary widely in cost. Ask your doctor to prescribe a generic preparation; then ask your pharmacist to fill it with the least expensive brand.

CYDEL® (W.E. Hauck, Inc.), see Cyclospasmol®.

PLAINTIFF'S EXHIBIT 26

PLAINTIFF'S EXHIBIT 27



PLAINTIFF'S EXHIBIT 28

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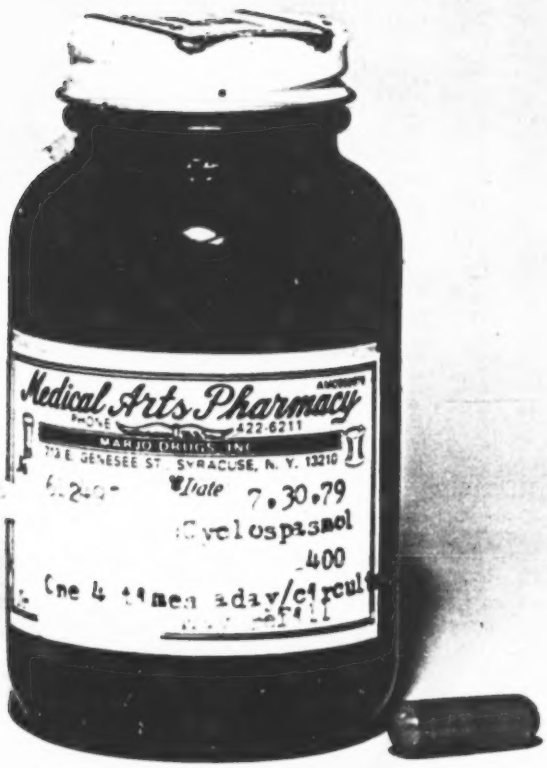

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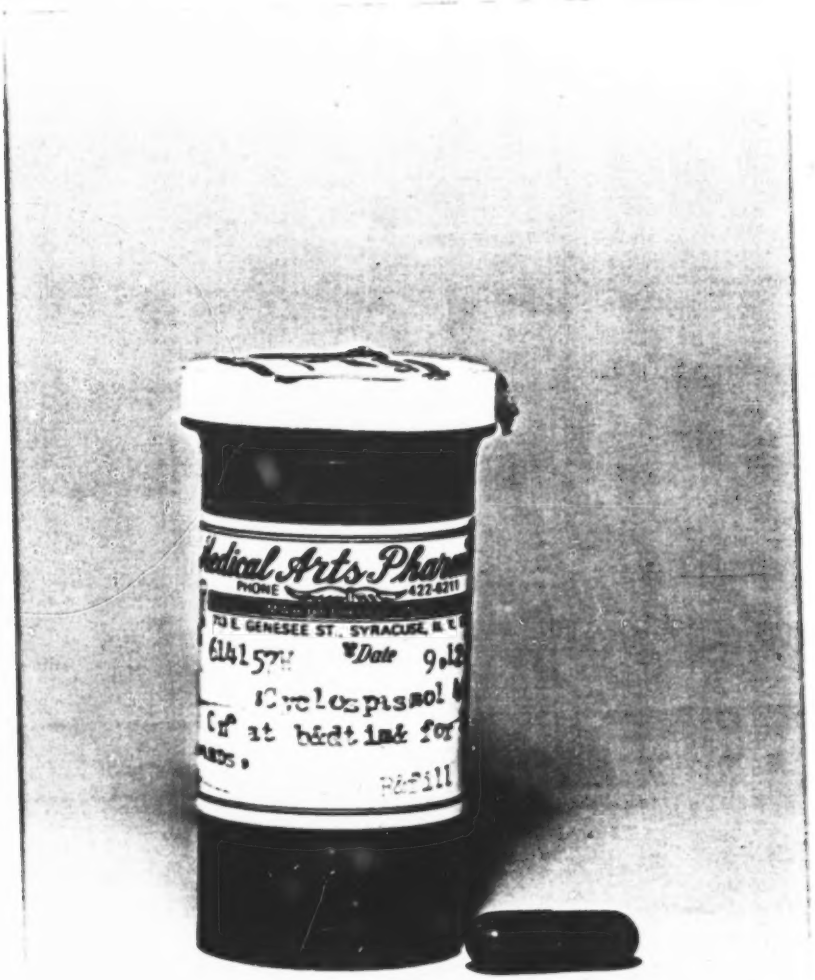
PLAINTIFF'S EXHIBIT 30



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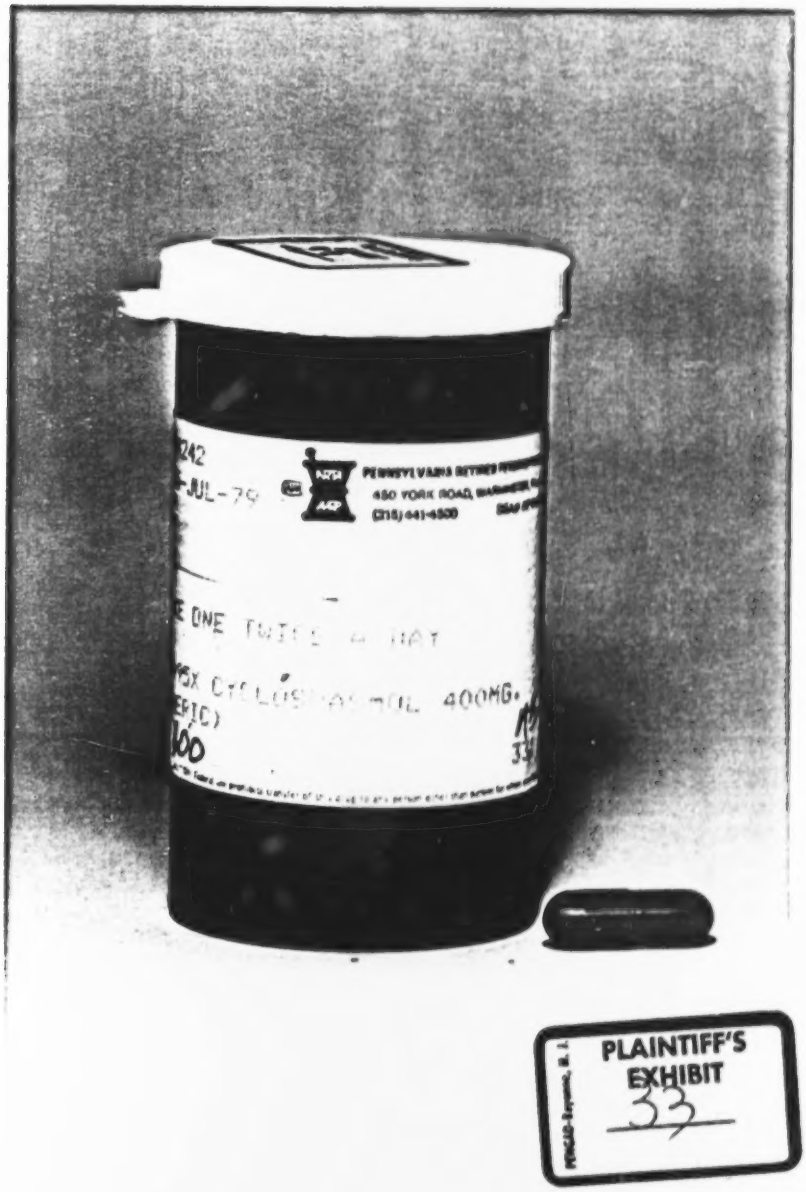

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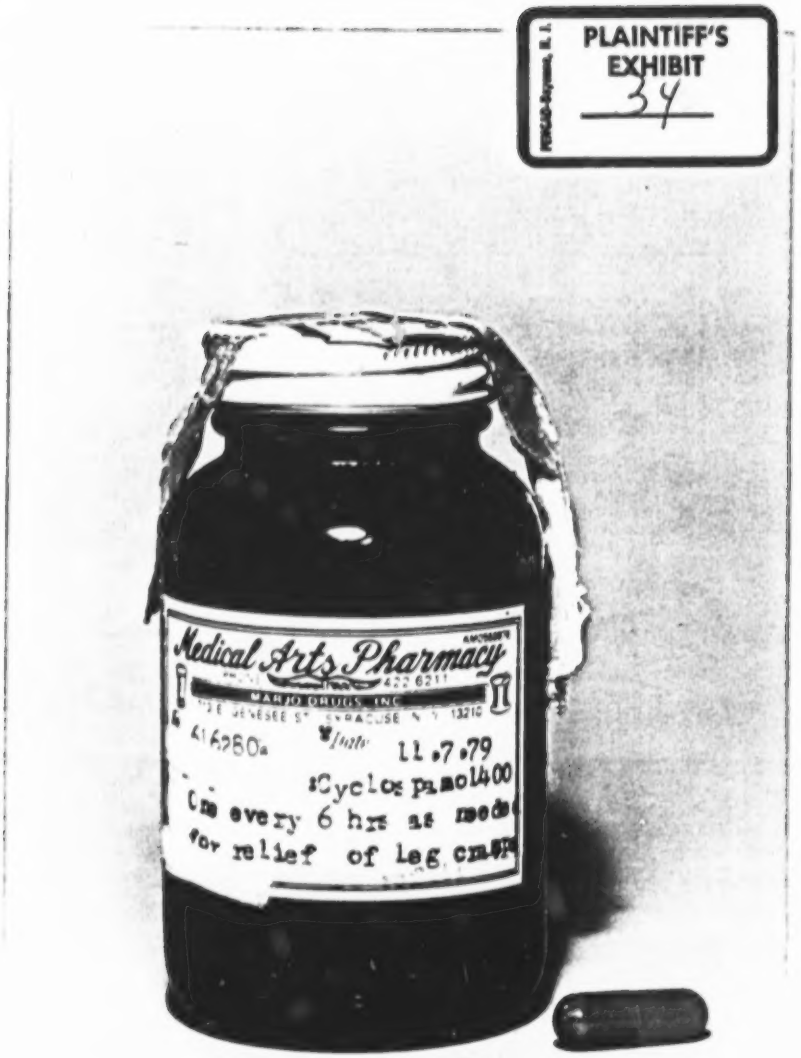

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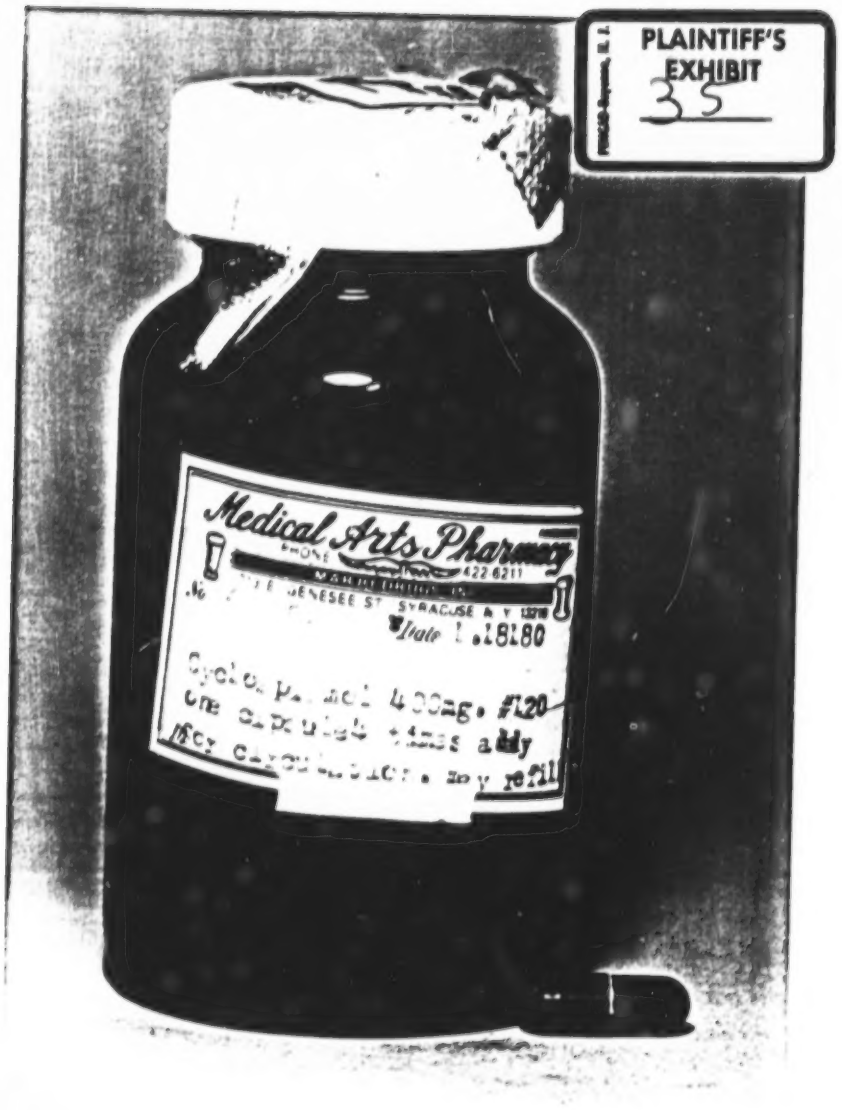

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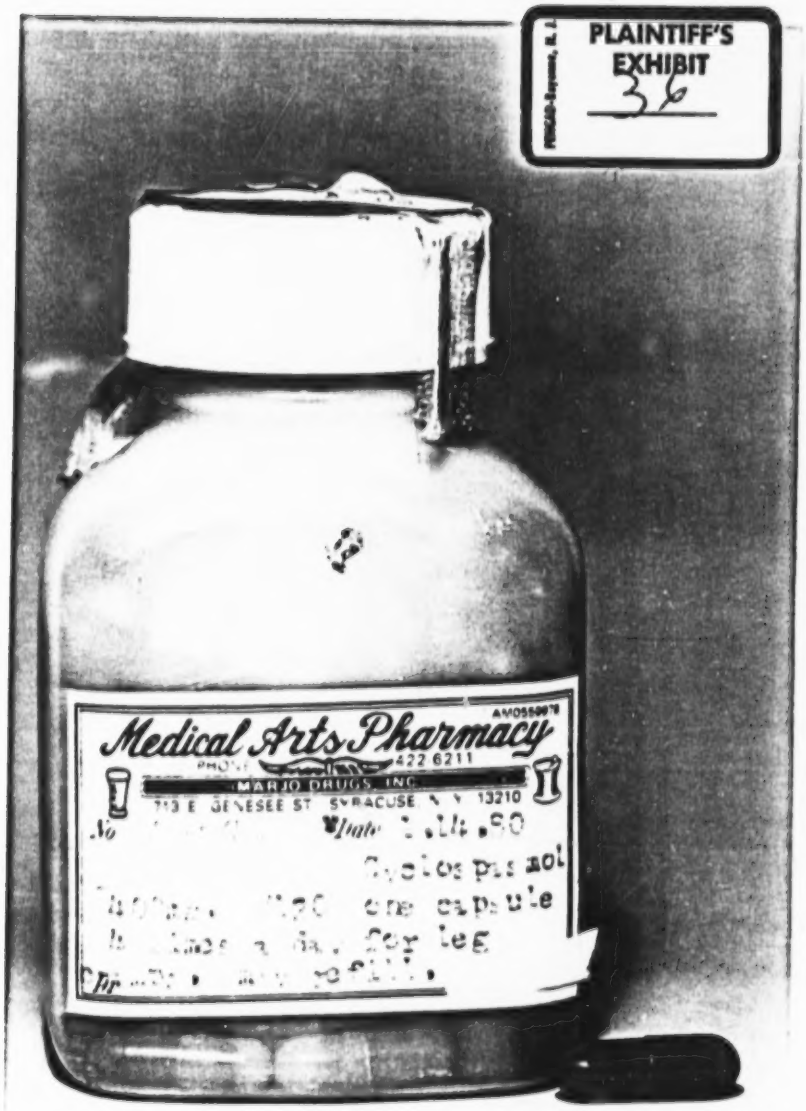

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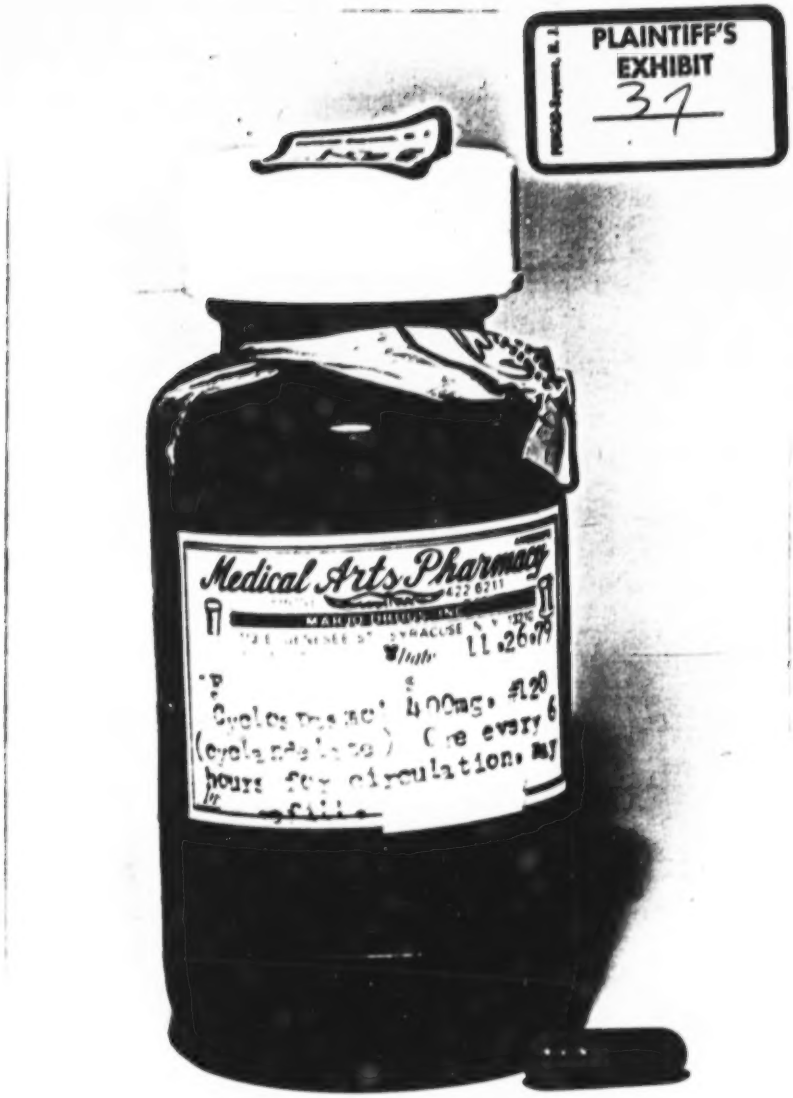

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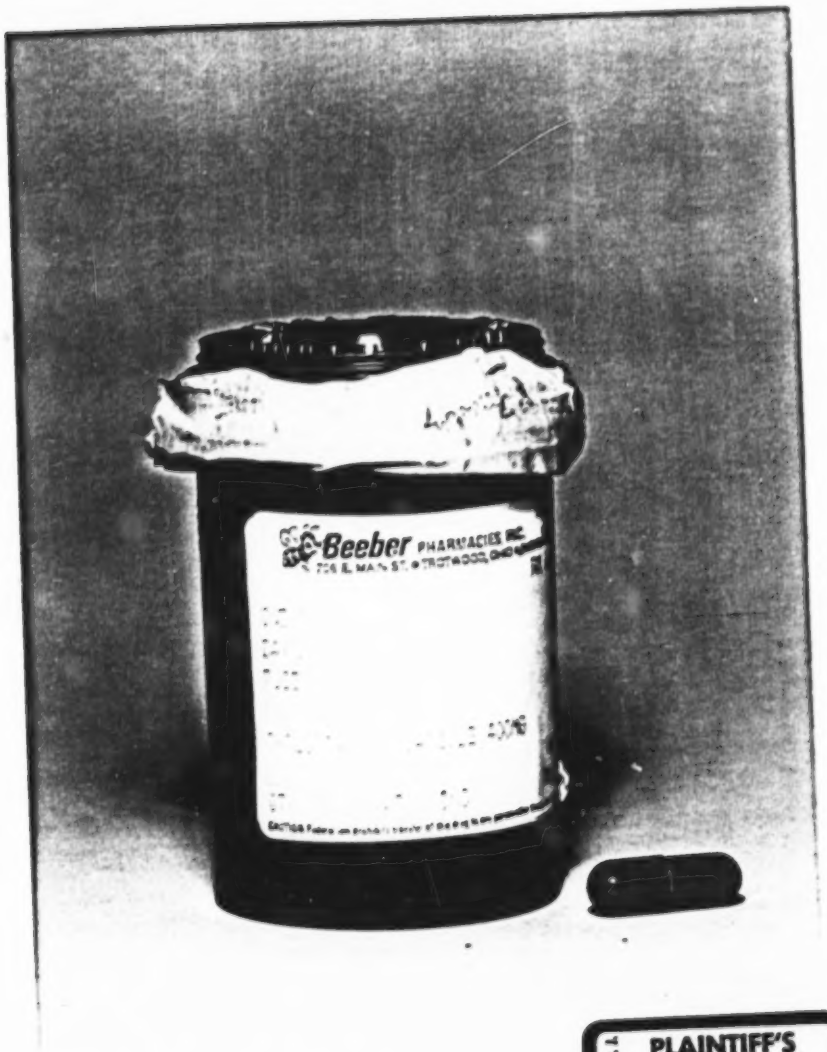
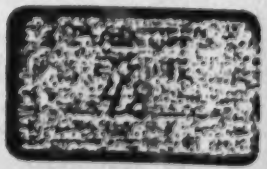


PLAINTIFF'S EXHIBIT 38

PLAINTIFF'S EXHIBIT 48



Plaintiff's Exhibit 48

creams

KENALOG and ARISTOCORT EQUIVALENT

ARISTALOG CREAM

(Triamcinolone Acetonide Cream, U.S.P.)

DESCRIPTION: Triamcinolone Acetonide in an aqueous, vanishing cream base containing propylene glycol, cetyl alcohol, glyceryl stearates, spermaceti (synthetic), isopropyl palmitate, polysorbate 60 and polysorbate 80.

0.025%	0935-35	15 g. tube
	0935-17	60 g. tube
	0935-20	5 lb. jar
0.1%	0937-35	15 g. tube
	0937-17	60 g. tube
	0937-20	5 lb. jar
0.5%	0939-35	15 g. tube
	0939-08	6 oz. jar

MYCOLOG EQUIVALENT

MYCO ARISTALOG CREAM

(Nystatin-Neomycin Sulfate-Gramicidin-Triamcinolone Acetonide Cream)

DESCRIPTION: This product, Nystatin-Neomycin Sulfate-Gramicidin-Triamcinolone Acetonide Cream combines, in each gram of aqueous, tinted, perfumed, vanishing cream base: triamcinolone acetonide 1 mg., nystatin 100,000 Units, neomycin sulfate equiv. to neomycin base 2.5 mg., gramicidin 0.25 mg.

The preparation also contains polysorbate 60, aluminum hydroxide concentrated wet gel, titanium dioxide, glyceryl monostearate, polyethylene glycol monostearate, simethicone emulsion, sorbic acid, propylene glycol, ethylenediamine hydrochloride, white petrolatum, polyoxyethylene fatty alcohol ether, methylparaben, propylparaben, and sorbitol solution.

0941-35	15 g. tube
0941-19	60 g. tube
0941-04	4 oz. jar
0941-16	1 lb. jar

MYCOSTATIN EQUIVALENT

NYSTATIN CREAM

DESCRIPTION: Nystatin Cream contains 100,000 units per gram of Nystatin, U.S.P. in an aqueous, perfumed, vanishing cream base containing aluminum hydroxide concentrated wet gel, titanium dioxide, sodium hydroxide, propylene glycol, polyoxyethylene fatty alcohol ether, white petrolatum, methylparaben, propylparaben, simethicone emulsion, sorbitol solution, glyceryl monostearate, and polyethylene glycol monostearate.

0955-35	15 g. tube

NOTE: All tubes supplied with peel off labels.

Plaintiff's Exhibit 48

tablets and capsules

ACTIFED EQUIVALENT
ACTI-HEM TABLETS

Each tablet contains:
Triprolidine HCl 2.5 mg.
Pseudoephedrine HCl 60 mg.

White, Compressed Tablet, Bisected

0979-01 Bottles of 100
0979-10 Bottles of 1000

APRESOLINE EQUIVALENT
HYDRALAZINE HCl TABLETS, U.S.P.

25 mg. Blue, Compressed Tablet

0945-01 Bottles of 100
0945-10 Bottles of 1000

50 mg. Pink, Compressed Tablet

0947-01 Bottles of 100
0947-10 Bottles of 1000

ARLIDIN EQUIVALENT
NYLIDRIN HCl TABLETS, N.F.

6 mg. White, Compressed Tablet, Bisected

0963-01 Bottles of 100
0963-10 Bottles of 1000

12 mg. White, Compressed Tablet, Bisected

0965-01 Bottles of 100
0965-10 Bottles of 1000

BENADRYL EQUIVALENT
DIPHENHYDRAMINE HCl CAPSULES, U.S.P.

25 mg. Pink & Clear, Hard Shell Capsule

0245-01 Bottles of 100
0245-10 Bottles of 1000

50 mg. Pink, Hard Shell Capsule

0247-01 Bottles of 100
0247-10 Bottles of 1000

CYCLOSPASMOL EQUIVALENT
CYCLANDELATE CAPSULES

200 mg. Powder Blue, Hard Shell Capsule

0919-01 Bottles of 100
0919-10 Bottles of 1000

400 mg. Red & Blue, Hard Shell Capsule

0977-01 Bottles of 100
0977-05 Bottles of 500
0977-10 Bottles of 1000

DARVON EQUIVALENT
PROPOXYPHENE HCl CAPSULES, U.S.P.

65 mg. Pink, Hard Shell Capsule

0741-01 Bottles of 100
0741-10 Bottles of 1000

DARVON COMP'D-65 EQUIVALENT
PROPOXYPHENE COMP'D-65 CAPSULES

Each capsule contains:
Propoxyphene HCl 65 mg.
Aspirin 227 mg. (3½ gr.)
Phenacetin 162 mg. (2½ gr.)
Caffeine 32.4 mg. (½ gr.)

Red & Grey, Hard Shell Capsule

0783-01 Bottles of 100
0783-05 Bottles of 500
0783-10 Bottles of 1000

DILANTIN EQUIVALENT
PHENYTOIN SODIUM CAPSULES, U.S.P.

100 mg. (1½ gr.) Clear, Hard Shell Capsule

0857-01 Bottles of 100
0857-10 Bottles of 1000

DIMETANE EQUIVALENT
BROMPHENIRAMINE MALEATE TABLETS, N.F.

4 mg. Peach, Compressed Tablet, Bisected

0995-01 Bottles of 100
0995-10 Bottles of 1000

DIMETAPP EXTENTABS EQUIVALENT
PHENATAPP EXTENDED ACTION TABLETS

Each tablet contains:
Brompheniramine Maleate 12 mg.
Phenylephrine HCl 15 mg.
Phenylpropanolamine HCl 15 mg.

Sky Blue, Sugar Coated Extended Action Tablet

0901-01 Bottles of 100
0901-10 Bottles of 1000

DISOPHROL CHRONOTAB EQUIVALENT
DISOHIST SUSTAINED ACTION TABLETS

Each tablet contains:
Dexbrompheniramine Maleate, not N.F., 6 mg.
D-isoephedrine Sulfate 120 mg.

Red, Sugar Coated, Extended Action Tablet

0993-01 Bottles of 100
0993-05 Bottles of 500

DRIXORAL EQUIVALENT
DRIXOHIST SUSTAINED ACTION TABLETS

Each tablet contains:
Dexbrompheniramine Maleate, not N.F., 6 mg.
D-isoephedrine Sulfate 120 mg.

Green, Sugar Coated, Extended Action Tablet

0981-01 Bottles of 100
0981-05 Bottles of 500

Plaintiff's Exhibit 48

ESIDRIX EQUIVALENT
HYDROCHLOROTHIAZIDE TABLETS, U.S.P.

50 mg. Yellow, Compressed Tablet, Bisected

0778-01	Bottles of 100
0778-10	Bottles of 1000

FOLIC ACID TABLETS, U.S.P.

1 mg. Yellow, Compressed Tablet, Bisected

0843-01	Bottles of 100
0843-10	Bottles of 1000

HYDROCORTISONE TABLETS, U.S.P.

20 mg. White, Compressed Tablet, Bisected

0329-01	Bottles of 100

HYDRODIURIL EQUIVALENT
HYDROCHLOROTHIAZIDE TABLETS, U.S.P.

25 mg. Peach, Compressed Tablet, Bisected

0777-01	Bottles of 100
0777-10	Bottles of 1000

50 mg. Peach, Compressed Tablet, Bisected

0779-01	Bottles of 100
0779-10	Bottles of 1000

HYDROPRES EQUIVALENT
HYDRO-SERP TABLETS

"25" . . . Each tablet contains:
Hydrochlorothiazide 25 mg.
Reserpine 0.125 mg.

Green, Compressed Tablet, Bisected

0923-01	Bottles of 100
0923-10	Bottles of 1000

"50" . . . Each tablet contains:
Hydrochlorothiazide 50 mg.
Reserpine 0.125 mg.

Green, Compressed Tablet, Bisected

0921-01	Bottles of 100
0921-10	Bottles of 1000

MAALOX EQUIVALENT
ALU-MAG TABLETS

A balanced formulation of Magnesium and Aluminum Hydroxides

White, Compressed Tablet, Bisected

0891-10	Bottles of 1000

MEPROBAMATE TABLETS, U.S.P.

200 mg., White, Compressed Tablet

0365-10	Bottles of 1000

400 mg., White, Compressed Tablet, Bisected

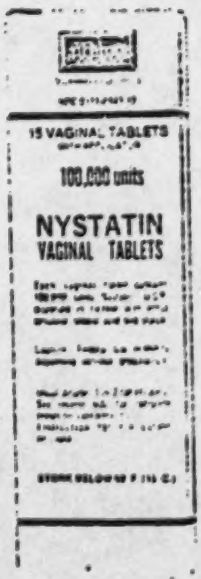
0367-10	Bottles of 1000

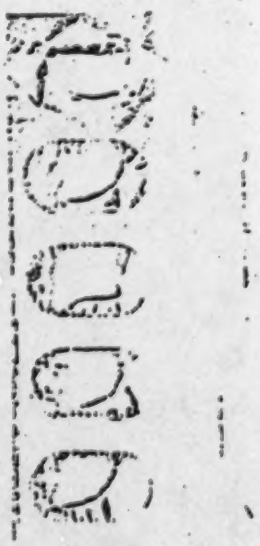
MYCOSTATIN VAGINAL EQUIVALENT
NYSTATIN VAGINAL TABLETS, U.S.P.

100,000 Units, Pale Yellow Compressed Tablet, Diamond Shape

0934-15	Packages of 15
0934-30	Packages of 30

Individually foil wrapped tablets with applicator and "Instructions for the patient" leaflet.





Instructions
For The Patient

Plaintiff's Exhibit 48

NORFLEX EQUIVALENT
ORPHENADRINE CITRATE TABLETS

100 mg. White, Compressed Tablets

0915-01	Bottles of 100
0915-05	Bottles of 500
0915-10	Bottles of 1000

PREDNISOLONE TABLETS, U.S.P.

5 mg. Orange, Compressed Tablet, Bisected

0507-01	Bottles of 100
0507-10	Bottles of 1000

PREDNISONE TABLETS, U.S.P.

5 mg. White, Compressed Tablet, Bisected

0509-01	Bottles of 100
0509-10	Bottles of 1000

SER-AP-ES EQUIVALENT
RESERPINE, HYDRALAZINE HCl AND HYDROCHLOROTHIAZIDE TABLETS

Each tablet contains:
Hydrochlorothiazide 15 mg.
Hydralazine HCl 25 mg.
Reserpine 0.1 mg.

Salmon, Compressed Tablet

0887-01	Bottles of 100
0887-10	Bottles of 1000

SUDAFED EQUIVALENT
PSEUDOEPHEDRINE HCl TABLETS, N.F.

60 mg. White, Compressed Tablet, Bisected

0917-01	Bottles of 100
0917-10	Bottles of 1000

TYLENOL EQUIVALENT
ACETAMINOPHEN TABLETS, U.S.P.

325 mg. (5 gr.) White, Compressed Tablet, Bisected

0839-01	Bottles of 100
0839-10	Bottles of 1000

TOFRANIL EQUIVALENT
IMIPRAMINE HCl TABLETS, U.S.P.

10 mg. Coral, Sugar Coated Tablet, Triangular Shape

0925-01	Bottles of 100
0925-10	Bottles of 1000

25 mg. Coral, Sugar Coated Tablet

0927-01	Bottles of 100
0927-10	Bottles of 1000

50 mg. Coral, Sugar Coated Tablet

0929-01	Bottles of 100
0929-10	Bottles of 1000

VASODILAN EQUIVALENT
ISOXSUPRINE HCl TABLETS, N.F.

10 mg. White, Compressed Tablet, Imprinted "10"

0911-01	Bottles of 100
0911-10	Bottles of 1000

20 mg. White, Compressed Tablet, Bisected, Imprinted "20"

0913-01	Bottles of 100
0913-05	Bottles of 500
0913-10	Bottles of 1000

Plaintiff's Exhibit 48

ACTIFED EQUIVALENT
ACTI-PHEN SYRUP

Neutral flavor, Yellow color

Each 5 ml. contains:
Triprolidine HCl 1.25 mg.
Pseudoephedrine HCl 30 mg.

0991-04	4 oz. Bottle
0991-16	16 oz. Bottle
0991-28	Gallon Bottle

AMPHOJEL EQUIVALENT
ALUMINUM HYDROXIDE GEL

Peppermint Flavor, White Color

Each 5 ml. contains:
Colloidal Aluminum Hydroxide Gel

0873-07	12 oz. Bottle
0873-28	Gallon Bottle

BENADRYL EQUIVALENT
DIPHENHYDRAMINE HCl ELIXIR

Aromatic flavor, Red color

Each 5 ml. contains:
Diphenhydramine HCl 12.5 mg.
Alcohol 14%

0889-04	4 oz. Bottle
0889-16	16 oz. Bottle
0889-28	Gallon Bottle

BENYLIN EQUIVALENT
DIPHENHYDRAMINE HCl
EXPECTORANT

Cherry-Raspberry flavor, Red color

Each 5 ml. contains:
Diphenhydramine HCl 12.5 mg.
Ammonium Chloride 125 mg.
Sodium Citrate 50 mg.
Menthol 1 mg.
Alcohol 5%

0893-04	4 oz. Bottle
0893-16	16 oz. Bottle
0893-28	Gallon Bottle

DIMETANE EQUIVALENT
PHENATANE EXPECTORANT

Cherry flavor, Pale Pink color

Each 5 ml. contains:
Brompheniramine Maleate, N.F. 2 mg.
Phenylephrine HCl, U.S.P. 5 mg.
Phenylpropanolamine HCl, N.F. 5 mg.
Guaifenesin, N.F. 100 mg.
Alcohol 3.5%

0763-04	4 oz. Bottle
0763-16	16 oz. Bottle
0763-28	Gallon Bottle

DIMETAPP EQUIVALENT
PHENATAPP ELIXIR

Grape flavor, Purple color

Each 5 ml. contains:
Brompheniramine Maleate, N.F. 4 mg.
Phenylephrine HCl, U.S.P. 5 mg.
Phenylpropanolamine HCl, N.F. 5 mg.
Alcohol 2.3%

0761-04	4 oz. Bottle
0761-16	16 oz. Bottle
0761-28	Gallon Bottle

DONNATOL EQUIVALENT
BELLADOL ELIXIR

Orange flavor, Green color

Each 5 ml. contains:
Hyoscyamine Sulfate 0.1037 mg.
Atropine Sulfate 0.0194 mg.
Hyoscine Hydrobromide 0.0085 mg.
Phenobarbital (1/4 gr.) 16.2 mg.
Alcohol 23%

0877-04	4 oz. Bottle
0877-16	16 oz. Bottle
0877-28	Gallon Bottle

ELIXOPHYLLIN EQUIVALENT
THEOPHYLLINE ELIXIR

Orange Flavor, Orange color

Each 15 ml. contains:
Theophylline (Anhydrous) 80 mg.
Alcohol 20%
in a palatable aromatic base.

0623-04	4 oz. Bottle
0623-16	16 oz. Bottle
0623-28	Gallon Bottle

KAY CIEL EQUIVALENT
POTASSIUM CHLORIDE
LIQUID CONC.

10%, Sugar Free, Orange color

Each 15 ml. contains:
Potassium Chloride 1.5 g.
(supplying 20 mEq.)
Alcohol 4%

0701-04	4 oz. Bottle
0701-16	16 oz. Bottle
0701-28	Gallon Bottle

KAOCHLOR EQUIVALENT
POTASSIUM CHLORIDE
LIQUID CONC.

20%, Sugar Free, Red color

Each 15 ml. contains:
Potassium Chloride 3 g.
(supplying 40 mEq.)
Alcohol 5%

0730-04	4 oz. Bottle
0730-16	16 oz. Bottle
0730-28	Gallon Bottle

KAOCHLOR WITH SUGAR EQUIVALENT
POTASSIUM CHLORIDE
LIQUID CONC.

10%, with Sugar, Yellow color

Each 15 ml. contains:
Potassium Chloride 1.5 g.
(supplying 20 mEq.) with sugar
Alcohol 5%

0951-04	4 oz. Bottle
0951-16	16 oz. Bottle
0951-28	Gallon Bottle

MAALOX EQUIVALENT
ALU-MAG ANTACID
SUSPENSION

Mint flavor, White color

A balanced formulation of Magnesium
and Aluminum Hydroxides

0875-07	12 oz. Bottle
0875-28	Gallon Bottle

PHENERGAN EQUIVALENT
PROMETHAZINE EXPECTORANT
Plain

Cherry flavor, Green color

Each 5 ml. contains:
Promethazine HCl 6 mg.
Alcohol 7%

0697-04	4 oz. Bottle
0697-16	16 oz. Bottle
0697-28	Gallon Bottle

ROBITUSSIN EQUIVALENT
GLYCOTUSSIN SYRUP

Cherry-Raspberry flavor, Red color

Each 5 ml. contains:
Guaifenesin, N.F. 100 mg.
Alcohol 3.5%

0881-04	4 oz. Bottle
0881-16	16 oz. Bottle
0881-28	Gallon Bottle

SUDAFED EQUIVALENT
SUDA-PHEN SYRUP

Cherry-Raspberry flavor, Red color

Each 5 ml. contains:
Pseudoephedrine HCl 30 mg.

0909-04	4 oz. Bottle
0909-16	16 oz. Bottle
0909-28	Gallon Bottle

Plaintiff's Exhibit 48

terms and general information

GUARANTEE: All products are guaranteed to be in accordance with the Federal Food, Drug and Cosmetic Act under the provisions of Sections 404 and 405, and amendments thereto.

MINIMUM ORDER: $250.00 minimum order; freight paid to destination. (Liquids $500 minimum order freight paid east of the Mississippi.) Call TOLL FREE (800) 631-0734 for quotations on your requirements. (Outside of Continental U.S. all shipments F.O.B. origin)

TERMS OF PAYMENT: 1% - 10 days, net 30 from date of invoice. Customer accepts title of shipment upon delivery to carrier.

CLAIMS: All claims must be made within 10 days after receipt of merchandise and are to be accompanied by date of purchase, invoice number and lot number.

RETURNS: All returns must be authorized in writing. Return authorization will include special shipping labels which must be affixed to your return.

SERVICES:

1. Analytical reports will be furnished upon request.
2. Samples of all products available upon request.
3. A certificate of product liability insurance is available upon request.
4. Arrangements can be made for private labeling of stock products, and private formulae.

CALL OUR WATS LINE TODAY

(800) 631-0734

General Offices (201) 343-5000

August 1976

Plaintiff's Exhibit 48

Premo Pharmaceutical Laboratories, Inc.
(Division of Omega Medical Systems)
111 Leuning St., So. Hackensack, N.J. 07606 / (201) 343-5000

"Pioneers in Generics"

BILL TO:

SHIP TO:

TO BE COMPLETED BY CUSTOMER		
Order No.	Date	BNDD Reg. No.

TO BE COMPLETED BY PREMO		
Terms	Freight	Special Instructions

PREMO NDC 0331-	TABLETS and CAPSULES	
C 0830-01	ACETAMINOPHEN TABLETS	1.25
M 0830-10	5 gr. White (Comp. to Tylenol)	9.98
C 0907-01	ACETAMINOPHEN TABLETS	1.25
M 0907-10	5 gr. Yellow (Comp. to Nebs)	9.98
M 0851-10	BELLADOL TABLETS (Comp. to Donnatal)	2.40
M 0155-10	CHLORPHENIRAMINE MALEATE T.D. CAPS. 8 mg. (Comp. to Teldrin)	9.98
M 0157-10	CHLORPHENIRAMINE MALEATE T.D. CAPS. 12 mg. (Comp. to Teldrin)	10.98
M 0161-10	CHLORPHENIRAMINE MALEATE TABS., 4 mg. (Comp. to Chlor-Trimeton)	2.48
C 0919-01	CYCLANDELATE CAPSULES	4.02
M 0919-10	200 mg. (Comp. to Cyclospasmol)	35.15
M 0855-10	D-CONGEST T.D. CAPSULES (Comp. to Ornade)	16.00
M 0745-10	DIOCTYL SOD. SULFOSUCCINATE CAPS. 100 mg. (Comp. to Colace)	12.20
M 0747-10	D.S.S. with CASANTHRANOL CAPS. (Comp. to Peri-Colace)	15.75
M 0245-10	DIPHENHYDRAMINE HCl CAPSULES 25 mg., (Comp. to Benadryl)	7.98
M 0247-10	DIPHENHYDRAMINE HCl CAPSULES 50 mg. (Comp. to Benadryl)	8.48
M 0857-10	DIPHENYLHYDANTOIN SODIUM CAPS. 100 mg. (Comp. to Dilantin)	9.31
C 0785-01	FERROUS GLUCONATE TABLETS	.76
M 0785-10	5 gr. (Comp. to Fergon)	4.44
M0281-10	FERROUS SULFATE T.D. CAPSULES 150 mg. (Comp. to Feosol spansules)	9.46
M 0281-10	FERROUS SULFATE TABLETS 5 gr. (Comp. to Feosol)	3.80
M 0813-10	FOLIC ACID TABLETS, 1 mg.	4.52
M 0587-10	HYDRAP-ES TABLETS (Comp. to Ser-Ap-Es)	19.80
M 0777-10	HYDROCHLOROTHIAZIDE TABLETS, 25 mg. (Comp. to Hydrodiuril)	6.66
M 0779-10	HYDROCHLOROTHIAZIDE TABLETS, 50 mg. (Comp. to Hydrodiuril)	8.95
C 0911-01	ISOXSUPRINE HCl TABLETS	3.92
M 0911-10	10 mg. (Comp. to Vasodilan)	34.94
C 0913-01	ISOXSUPRINE HCl TABLETS	6.66
5C 0913-05	20 mg. (Comp. to Vasodilan)	31.58
M 0913-10		59.80

PREMO NDC 0331-	TABLETS and CAPSULES	
M 0367-10	MEPROBAMATE TABLETS 400 mg. (Comp. to Equanil)	6.68
5C 0905-05	METHOCARBAMOL TABLETS 500 mg. (Comparable to Robaxin)	24.00
5C 0903-05	METHOCARBAMOL TABLETS 750 mg. (Comparable to Robaxin)	32.00
C 0817-01	NITROFURANTOIN CAPSULES	6.95
5C 0817-05	50 mg. (Comp. to Macrodantin)	33.00
C 0819-01	NITROFURANTOIN CAPSULES	11.60
5C 0819-05	100 mg. (Comp. to Macrodantin)	55.00
C 0915-01	ORPHENADRINE CITRATE TABLETS	5.25
5C 0915-05	100 mg. (Comp. to Norflex)	26.60
M 0727-10	PAPAVERINE HCl T.D. CAPS 150 mg. (Comp. to Pavabid)	24.00
M 0253-10	PHENAZOPYRIDINE HCl TABLETS. 100 mg. (Comp. to Pyridium)	9.98
M 0901-10	PHENATAPP TABLETS, Extended Action (Comp. to Dimetapp Extentabs)	27.50
M 0507-10	PREDNISOLONE TABLETS 5 mg.-Light Orange	P.O.R.
M 0500-10	PREDNISONE TABLETS 5 mg.-White	P.O.R.
5C 0783-05	PROPOXYPHENE COMPOUND 65 CAPSULES (Comp. to Darvon Compound)	9.50
M 0741-10	PROPOXYPHENE HCl CAPSULES 65 mg. (Comp. to Darvon)	16.00
M 0917-10	PSEUDOEPHEDRINE HCl TABLETS 60 mg. (Comp. to Sudafed)	14.85
M 0850-10	RESERPINE TABLETS	1.98
5M 0850-55	0.25 mg. (Comp. to Serpasil)	3.68
M 0861-10	SULFISOXAZOLE TABLETS 500 mg. (Comp. to Gantrisin)	14.56
M 0863-10	THEOPHENEDRINE TABLETS (Comp. to Tedral)	6.50
C 0750-01	TOLBUTAMIDE TABLETS	5.35
5C 0750-05	0.5 g. (Comp. to Orinase)	24.30

Rx Only

EFFECTIVE APRIL 1, 1975
PRICES SUBJECT TO CHANGE WITHOUT NOTICE

Plaintiff's Exhibit 48

VITAMINS (Tablets - Capsules)

PREMO NDC 0331		
0291-01	MULTIPLE VITAMINS - Red	.72
0291-10	(Comp. to One-a-day)	4.48
0293-01	MULTIPLE VITAMINS w/IRON	.76
[illegible]	Yellow (Comp. to One a-day w/ IRON	4.76
[illegible]	THERA-FORM TABLETS	1.56
0821-10	(Comp. to Theragran)	12.26
0823-01	THERA-FORM M TABLETS	1.68
[illegible]	(Comp. to Theragran M)	13.38
0971-01	VITAMIN B COMPLEX with C CAPS.	1.65
[illegible]	(Comp. to Allbee w/C)	14.56
[illegible]	VITAMIN C TABLETS, 250 mg.	.84
[illegible]	(ASCORBIC ACID)	7.78
[illegible]	VITAMIN C TABLETS, 500 mg	1.43
[illegible]	(ASCORBIC ACID)	10.95
[illegible]	VITAMIN E CAPSULES, 100 I.U	1.52
[illegible]	(From dl Alpha Tocopheryl Acetate)	9.30
[illegible]	VITAMIN E CAPSULES, 200 I.U	2.04
[illegible]	(From dl Alpha Tocopheryl Acetate)	16.32
[illegible]	VITAMIN E CAPSULES, 400 I.U	3.36
[illegible]	(From dl Alpha Tocopheryl Acetate)	29.28

NEW PRODUCTS - TABLETS & CAPSULES

[illegible]	HYDRO-SERP (25) TABLETS	7.80
[illegible]	(Comp. to Hydropres)	
[illegible]	HYDRO-SERP (50) TABLETS	15.50
[illegible]	(Comp. to Hydropres)	

LIQUIDS

	PREMO NDC 0331		
—	12 oz	0873-07	ALUMINUM HYDROXIDE GEL .67•
—	gal.	0873-28	(Comp. to Amphojel) 6.68
—	12 oz.	0875-07	ALU MAG LIQUID .67•
—	gal.	0875-28	(Comp. to Maalox) 6.68
—	4 oz.	0877-04	BELLADOL ELIXIR .61:
—	gal.	0877-28	(Comp. to Donnatal) 10.40
—	4 oz.	0889-04	DIPHENHYDRAMINE HCl ELIXIR .50:
—	gal	0889-28	(Comp. to Benadryl) 8.98
—	4 oz	0893-04	DIPHENHYDRAMINE HCl .53:
—	gal.	0893-28	EXPECTORANT (Comp. to Benylin) 9.98
—	4 oz.	0881-04	GLYCERYL GUAIACOLATE SYRUP .45:
—	gal.	0881-28	(Comp. to Robitussin) 8.90
—	4 oz.	0763-04	PHENATANE EXPECTORANT .62:
—	gal.	0763-28	(Comp. to Dimetane) 10.78
—	4 oz.	0761-04	PHENATAPP ELIXIR .58:
—	gal	0761-28	(Comp. to Dimetapp) 9.44
—	4 oz	0701-04	POTASSIUM CHLORIDE LIQ. CONC .50:
—	pint	0701-16	10% (Comp. to Kay Ciel) 1.17•
—	gal.	0701-28	7.28
—	4 oz.	0739-04	POTASSIUM CHLORIDE LIQ. CONC .50:
—	pint	0739-16	20% (Comp. to Kay Ciel) 1.17•
—	gal.	0739-28	7.28
—	4 oz.	0797-04	PROMETHAZINE EXPECTORANT .55:
—	gal.	0797-28	(Comp. to Phenergan) 11.28
—	4 oz.	0909-04	PSEUDOEPHEDRINE HCl SYRUP .89:
—	pints	0909-16	(Comp. to Sudafed) 2.80•
—	gal.	0909-28	13.38
—	4 oz.	0603-04	TERPIN HYDRATE D.M. ELIXIR .60:
—	gal.	0603-28	11.50
—	pint	0623-16	THEOPHYLLINE ELIXIR 1.25•
—	gal.	0623-28	(Comp. to Elixophyllin) 8.50:

NEW PRODUCTS - LIQUIDS

—	pint	0885-16	THEOPHYLLINE K.I. 1.80•
—	gal.	0885-28	(Comp. to Elixophyllin K.I.) 12.90

Gallons packaged 4 to a case
• packaged 12 to a case
: packaged 24 to a case

Plaintiff's Exhibit 48

TABLETS AND CAPSULES

PREMO BRAND

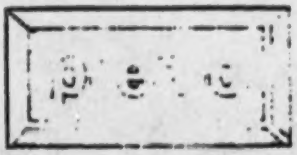
Algemol Velvetabs
Chlordinium Sealets[R]
Chlorzoxazone with Acetaminophen Tablets
Cyclandelate Capsules 200mg. and 400mg.
Hydralazine HCl Tablets 25mg. and 50mg.
Imipramine HCl Tablets 25mg.
Isoxsuprine HCl Tablets 10mg. and 20mg.
Phenatapp Extended Action Tablets
Nystatin Vaginal Tablets
Theophedrizine Tablets
Tolbutamide Tablets

Gaviscon Tablets
Librax Capsules
Parafon Forte Tablets
Cyclospasmol Capsules
Apresoline Tablets
Tofranil Tablets
Vasodilan Tablets
Dimetapp Tablets
Mycostatin Vaginal Tablets
Marax Tablets
Orinase Tablets

CREAMS

Myco Triacet Cream
Nystatin Cream
Triacet Cream 0.025%, 0.1%, 0.5%

Mycolog Cream
Mycostatin Cream
Kenalog and Aristacort



"Pioneers in Generics"

Premo Pharmaceutical Laboratories, Inc.

111 LEUNING ST., SO. HACKENSACK, N.J. U.S.A. 07606 / (201) 343-5000

Plaintiff's Exhibit 48

Premo Pharmaceutical Laboratories, Inc.
(Division of Omega Medical Systems)
111 LEUNING ST., SO. HACKENSACK, N.J., U.S.A. 07606 / (201) 343-8000

"Pioneers in Generics"

TABLETS AND CAPSULES

PREMO BRAND

Acti-Prem Tablets	Actifed Tablets
Algemol Velvetabs	Gaviscon Tablets
Chlordinium Sealets®	Librax Capsules
Cyclandelate Capsules 200mg. & 400mg.	Cyclospasmol Capsules
Diphenhydramine HCl Capsules 25mg. & 50mg.	Benadryl Capsules
Hydralazine HCl Tablets 25mg. & 50mg.	Apresoline Tablets
Imipramine HCl Tablets 25mg.	Tofranil Tablets
Isoxsuprine HCl Tablets 10mg. & 20mg.	Vasodilan Tablets
Nylidrin HCl Tablets 6mg. & 12mg.	Arlidin Tablets
Phenatapp Extended Action Tablets	Dimetapp Tablets
Pseudoephedrine HCl Tablets 60mg.	Sudafed Tablets
Nystatin Vaginal Tablets	Mycostatin Vaginal Tablets

CREAMS

Myco Triacet Cream	Mycolog Cream
Nystatin Cream	Mycostatin Cream
Triacet Cream .025%, .1% & .5%	Kenalog & Aristacort

*** NEW ADDITIONS ***

Chlorzoxazone with Acetaminophen Tablets	Parafon Forte Tablets
Tolbutamide Tablets 0.5 g.	Orinase Tablets

Sales Office Number - 201-343-8400

1/4/78

Plaintiff's Exhibit 48

111 LEONING ST., SO. HACKENSACK, N.J. U.S.A. 07606 PHONE (201) 343-3600 TELEX - 134652 PREMOLAB

"Pioneers in Generics"

TABLETS AND CAPSULES

PREMO BRAND

Acti-Prem Tablets	Actifed Tablets
Cyclandelate Capsules 200mg.	Cyclospasmol Capsules 200mg.
Cyclandelate Capsules 400mg.	Cyclospasmol Capsules 400mg.
Diphenhydramine HCl Capsules 25mg. ...	Benadryl Capsules 25mg.
Diphenhydramine HCl Capsules 50mg. ...	Benadryl Capsules 50mg.
Hydralazine HCl Tablets 25mg.	Apresoline Tablets 25mg.
Hydralazine HCl Tablets 50mg.	Apresoline Tablets 50mg.
Imipramine HCl Tablets 25mg.	Tofranil Tablets 25mg.
Isoxsuprine HCl Tablets 10mg.	Vasodilan Tablets 10mg.
Isoxsuprine HCl Tablets 20mg.	Vasodilan Tablets 20mg.
Nylidrin HCl Tablets 6mg.	Arlidin Tablets 6mg.
Nylidrin HCl Tablets 12mg.	Arlidin Tablets 12mg.
Phenatapp Extend Tablets	Dimetapp Tablets
Pseudoephedrine HCl Tablets 60mg.	Sudafed Tablets
Nystatin Vaginal Tablets	Mycostatin Vaginal Tablets

CREAMS

Myco Triacet Cream	Mycolog Cream
Nystatin Cream	Mycostatin Cream
Triacet Cream .025%	Kenalog or Aristacort Cream
Triacet Cream .1%	Kenalog or Aristacort Cream
Triacet Cream .5%	Kenalog or Aristacort Cream

******NEW ADDITIONS******

Chlordinium Sealets^{R}.....	Librax Capsules
Tribamate Tablets "200"	Pathibamate Tablets 200
Tribamate Tablets "400"	Pathibamate Tablets 400

5/1/78

7/20/77

Premo Pharmaceutical Laboratories, Inc.

Plaintiff's Exhibit 48

11 LEUNING ST., CO. HACKENSACK, N.J. U.S.A. 07606 PHONE (201) 343-5000, TELEX - 1[illegible] PREMOLABS SHA[illegible]

"Pioneers in Generics"

11/4/77

TABLETS AND CAPSULES

Acti-Prem Tablets	Actifed Tablets
Algemol Velvetabs	Gaviscon Tablets
Chlordinium Sealets[R]	Librax Capsules
Cyclandelate Capsules 200mg. and 400 mg.	Cyclospasmol Capsules
Diphenhydramine HCl Capsules 25mg. and 50 mg.	Benadryl Capsules
Hydralazine HCl Tablets 25mg. and 50mg.	Apresoline Tablets
Imipramine HCl Tablets 25mg.	Tofranil Tablets
Isoxsuprine HCl Tablets 10mg. and 20mg.	Vasodilan Tablets
Nylidrin HCl Tablets 6mg. and 12mg.	Arlidin Tablets
Phenatapp Extended Action Tablets	Dimetapp Tablets
Pseudoephedrine HCl Tablets 60mg.	Sudafed Tablets
Nystatin Vaginal Tablets	Mycostatin Vaginal Tablets

CREAMS

Myco Triacet Cream	Mycolog Cream
Nystatin Cream	Mycostatin Cream
Triacet Cream .025%, .1% and .5%	Kenalog and Aristacort

**** NEW ADDITIONS ****

Chlorzoxazone with Acetaminophen Tablets	Parafon Forte Tablets
Tolbutamide Tablet	Oranase Tablets

[illegible]
[illegible] 5/4/78

[illegible] Inc.

599a

Plaintiff's Exhibit 48

Premo Pharmaceutical Laboratories, Inc.
(Division of Omega Medical Systems)
111 LEUNING ST., SO. HACKENSACK, N.J., U.S.A. 07606 / (201) 343-5000

"Pioneers in Generics"

TABLETS AND CAPSULES

Acti-Prem Tablets	Actifed Tablets
Algemol Velvetabs	Gaviscon Tablets
Chlordinium Sealets[R]	Librax Capsules
Cyclandelate Capsules 200mg. and 400 mg.	Cyclospasmol Capsules
Diphenhydramine HCl Capsules 25mg. and 50 mg.	Benadryl Capsules
Hydralazine HCl Tablets 25mg. and 50mg.	Apresoline Tablets
Imipramine HCl Tablets 25mg.	Tofranil Tablets
Isoxsuprine HCl Tablets 10mg. and 20mg.	Vasodilan Tablets
Nylidrin HCl Tablets 6mg. and 12mg.	Arlidin Tablets
Phenatapp Extended Action Tablets	Dimetapp Tablets
Pseudoephedrine HCl Tablets 60mg.	Sudafed Tablets
Nystatin Vaginal Tablets	Mycostatin Vaginal Tablet

CREAMS

Myco Triacet Cream	Mycolog Cream
Nystatin Cream	Mycostatin Cream
Triacet Cream .025%, .1% and .5%	Kenalog and Aristacort

**** NEW ADDITIONS ****

Chlorzoxazone with Acetaminophen Tablets	Parafon Forte Tablets
Tolbutamide Tablets 0.5g *	Orinase Tablets

*Available for shipment on January 18, 1978

12/22/77

1/26/76

600a

Plaintiff's Exhibit 48

111 LEUNING ST., SO. HACKENSACK, N.J. U.S.A. 07606 premo PHONE (201) 343-5000, TELEX - 134652 PREMOLABS S

"Pioneers in Generics"

TABLETS & CAPSULES

Premo Equivalent Product	National Brand
Actaprem Tablets	Actifed Tablets
Hydralazine HCl Tablets 25 mg. & 50 mg.	Apresoline Tablets
Nylidrin HCl Tablets 6 mg & 12 mg	Arlidin Tablets
Cyclandelate Capsules 200 mg & 400 mg.	Cyclospasmol Capsules
Phenatapp Extend Tablets	Dimetapp Extend Tablets
Hydrochlorothiazide Tabs. 25 mg & 50 mg. (Peach and Yellow)	Esidrix and Hydro-Diuril Tablets
Hydro-Serp Tablets 25 mg. & 50 mg.	Hydropres Tablets
Hydrap-Es Tablets	Ser-Ap-Es Tablets
Pseudoephedrine HCl Tablets	Sudafed Tablets
Imipramine HCl Tabs. 10 mg, 25 mg & 50 mg	Tofranil Tablets
Isoxsuprine HCl Tabs. 10 mg and 20 mg	Vasodilan Tablets

LIQUIDS

Actaprem Syrup	Actifed Syrup
Diphenhydramine HCl Elixir	Benadryl Elixir
Diphenhydramine HCl Expectorant	Benylin Expectorant
Phenatane Expectorant	Dimetane Expectorant
Phenatapp Elixir	Dimetapp Elixir
Theophylline Elixir	Elixophyllin
Potassium Chloride 10% & 20%, Sugar-free, Red	Kay Ciel Elixir and Kaochlor Conc
Potassium Chloride 10% w/sugar, Yellow	Kaochlor 10% Liquid
Alu-Mag Antacid Suspension	Maalox Suspension
Promethazine Expectorant	Phenergan Expectorant Plain
Glyceryl Guiaicolate Expectorant	Robitussin Expectorant
Pseudoephedrine HCl Syrup	Sudafed Syrup

CREAMS

Aristalog Cream .025%, .1% and .5%	Kenalog or Aristacort Cream
Myco Aristalog Cream	Mycolog Cream
Nystatin Cream 100,000 Units	Mycostatin Cream
Nystatin Vaginal Tablets with Applicator	Mycostatin Vaginal Tablets

Px (Blackman) 9 fwd
vl 5/4/78

Call our Wats Line 800-631-0734
for price quotations.
Laura Jenin
Account Executive

Premo Pharmaceutical Laboratories, Inc.

Plaintiff's Exhibit 48

Premo Pharmaceutical Laboratories, Inc.
(Division of Omega Medical Systems)
111 Leuning St., So. Hackensack, N.J. 07606 / (201) 343-5000

Pioneers in Generics
Established 1927

PRICE LIST NO. 101

EFFECTIVE MARCH 10, 1976

TERMS AND CONDITIONS OF SALE

Payment terms: 1%, 10 Days, Net 30.

Analytical reports furnished on request.

Samples of all products available on request.

Certificate of product liability insurance available on request.

All orders subject to acceptance by the main office.

Arrangements can be made for private label.

Liquid products are shipped F.O.B. South Hackensack, N. J.; all others are shipped prepaid.

Guarantee: All products are guaranteed to be in accordance with the Federal Food, Drug and Cosmetic Act under the provisions of sections 404 and 405, and amendments thereto.

1. All prices are subject to change without notice.

2. All sales are outright.

3. All claims must be made within eight days after receipt of merchandise and are to be accompanied by date of purchase, invoice number and lot number.

4. Returns:
   All returns must be authorized, in writing, by Premo's main office.

FROM:

Name:_____

Address:_____

City:_____ State:_____ Zip:_____

By:_____ Date:_____

Plaintiff's Exhibit 48

Premo Pharmaceutical Laboratories, Inc.
(Division of Omega Medical Systems)
111 Leuning St., So. Hackensack, N.J. 07606 / (201) 343-5000

Pioneers in Generics
Established 1927

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Payment terms: 1%, 10 Days, Net 30.

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4. Returns:
   All returns must be authorized, in writing, by Premo's main office.

FROM:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

By: _____ Date: _____

Plaintiff's Exhibit 48

TABLETS AND CAPSULES

RATIONAL BRAND	PREMO EQUIVALENT PRODUCT	STRENGTH	SIZE	COLOR	PRICE PER BOTTLE 1,000 OR MORE	500 TO 999	250 TO 499	100 TO 249	25 TO 99	QUANTITY TO SHIP
APRESOLINE, 25 mg. TABS	HYDRALAZINE HCl TABS	25 mg.	100	Blue			.63	.46	.59	
APRESOLINE, 25 mg. TABS	HYDRALAZINE HCl TABS	25 mg.	1,000	Blue			5.25	5.11	5.57	
APRESOLINE, 50 mg. TABS	HYDRALAZINE HCl TABS	50 mg.	100	Pink		1.79	1.21	1.79	1.13	
APRESOLINE, 50 mg. TABS	HYDRALAZINE HCl TABS	50 mg.	1,000	Pink		3.29	3.27	3.55	3.84	
ARLIORIN, 3 mg. TABS	NYLIORIN HCl TABS	3 mg.	100	White		1.50	1.72	1.95	1.98	
ARLIORIN 6 mg. TABS	NYLIORIN HCl TABS	6 mg.	1,000	White		7.03	7.24	7.30	7.66	
ARLIORIN, 12 mg. TABS	NYLIORIN HCl TABS	12 mg.	100	White		1.50	1.54	1.58	1.65	
ARLIORIN, 12 mg. TABS	NYLIORIN HCl TABS	12 mg.	1,000	White		12.00	12.12	12.26	13.19	
CYCLOSPASMOL, 200 mg. CAPS	CYCLANDELATE CAPS	200 mg.	100	Pk Blue	2.10	2.10	2.22	2.10	2.25	
CYCLOSPASMOL, 200 mg. CAPS	CYCLANDELATE CAPS	200 mg.	1,000	Pk Blue		18.00	18.94	18.10	19.49	
CYCLOSPASMOL, 400 mg. CAPS	CYCLANDELATE CAPS	400 mg.	100	Red/Blue			3.70	3.81	3.93	
CYCLOSPASMOL, 400 mg. CAPS	CYCLANDELATE CAPS	400 mg.	500	Red/Blue			17.70	17.72	18.08	
CYCLOSPASMOL, 400 mg. CAPS	CYCLANDELATE CAPS	400 mg.	1,000	Red/Blue		34.00	35.02	35.07	35.79	
DIMETAPP EXTENTABS	PHENATAPP EXTEND TABS		100	Sky Blue	1.48	1.43	1.57	1.50	1.62	
DIMETAPP EXTENTABS	PHENATAPP EXTEND TABS		1,000	Sky Blue	12.00	12.26	12.73	13.11	13.37	
ESIDRIX, 25 mg. TABS	HYDROCHLOROTHIAZIDE TABS	25 mg.	100	Yellow	.68	.70	.72	.75	*	
ESIDRIX, 25 mg. TABS	HYDROCHLOROTHIAZIDE TABS	25 mg.	1,000	Yellow	2.75	3.02	3.23	4.01	4.03	
ESIDRIX, 50 mg. TABS	HYDROCHLOROTHIAZIDE TABS	50 mg.	100	Yellow	.74	.76	.79	.82	*	
ESIDRIX, 50 mg. TABS	HYDROCHLOROTHIAZIDE TABS	50 mg.	1,000	Yellow	4.25	4.37	4.52	4.58	4.62	
HYDRO-DIURIL, 25 mg. TABS	HYDROCHLOROTHIAZIDE TABS	25 mg.	100	Peach	.68	.70	.72	.74	*	
HYDRO-DIURIL, 25 mg. TABS	HYDROCHLOROTHIAZIDE TABS	25 mg.	1,000	Peach	2.75	2.86	2.95	3.07	3.19	
HYDRO-DIURIL, 50 mg. TABS	HYDROCHLOROTHIAZIDE TABS	50 mg.	100	Peach	.68	.70	.72	.76	*	
HYDRO-DIURIL, 50 mg. TABS	HYDROCHLOROTHIAZIDE TABS	50 mg.	1,000	Peach	3.75	3.89	3.98	4.19	4.18	
HYDROPRES, 25 TABS	HYDRO-SERP TABS 25		100	Green		.80	.81	.82	*	
HYDROPRES, 25 TABS	HYDRO-SERP TABS 25		1,000	Green			3.00	3.09	3.18	
HYDROPRES, 50 TABS	HYDRO-SERP TABS 50		100	Green		.71	.73	.77	*	
HYDROPRES, 50 TABS	HYDRO-SERP TABS 50		1,000	Green		4.25	4.38	4.61	4.68	
SER-AP-ES TABS	HYDRAP-ES TABS		100	Salmon	.83	.99	.99	1.02	1.04	
SER-AP-ES TABS	HYDRAP-ES TABS		1,000	Salmon	7.25	7.37	7.52	7.71	7.97	
SUDAFED 60 mg. TABS	PSEUDOEPHEDRINE HCl TABS	60 mg.	100	White	1.17	1.21	1.25	1.30	1.33	
SUDAFED 60 mg. TABS	PSEUDOEPHEDRINE HCl TABS	60 mg.	1,000	White	9.75	9.01	9.28	9.58	9.75	
TOFRANIL, 10 mg. TABS	IMIPRAMINE HCl TABS	10 mg.	100	Coral		1.56	1.61	1.67	1.70	
TOFRANIL, 10 mg. TABS	IMIPRAMINE HCl TABS	10 mg.	1,000	Coral		12.80	12.98	13.27	13.64	
TOFRANIL, 25 mg. TABS	IMIPRAMINE HCl TABS	25 mg.	100	Coral	2.34	2.41	2.48	2.55	2.60	
TOFRANIL, 25 mg. TABS	IMIPRAMINE HCl TABS	25 mg.	1,000	Coral	20.40	21.01	21.64	22.29	22.74	
TOFRANIL, 50 mg. TABS	IMIPRAMINE HCl TABS	50 mg.	100	Coral		2.94	3.00	3.09	3.15	
TOFRANIL, 50 mg. TABS	IMIPRAMINE HCl TABS	50 mg.	1,000	Coral		26.40	27.19	28.01	28.57	
VASODILAN, 10 mg. TABS	ISOXSUPRINE HCl TABS	10 mg.	100	White	2.73	2.86	2.95	3.04	3.19	
VASODILAN, 10 mg. TABS	ISOXSUPRINE HCl TABS	10 mg.	1,000	White	24.99	25.54	26.31	27.10	27.64	
VASODILAN, 20 mg. TABS	ISOXSUPRINE HCl TABS	20 mg.	100	White		5.01	5.16	5.31	5.47	
VASODILAN, 20 mg. TABS	ISOXSUPRINE HCl TABS	20 mg.	500	White		23.00	23.92	25.46	26.22	
VASODILAN, 20 mg. TABS	ISOXSUPRINE HCl TABS	20 mg.	1,000	White		47.12	48.53	49.99	52.49	

GOLD FOIL, STRIP TAPED TABLETS

RATIONAL BRAND	PREMO EQUIVALENT PRODUCT	STRENGTH	SIZE	COLOR	PRICE PER BOX 1,584 OR MORE	1,008 TO 1,440	576 TO 864	144 TO 432	QUANTITY TO SHIP
MYCOSTATIN VAGINAL TABS 100 mg.	NYSTATIN VAGINAL TABS w/ applicator	100 mg.	15	Pale Yellow	1.00	1.03	1.06	1.09	
MYCOSTATIN VAGINAL TABS 100 mg.	NYSTATIN VAGINAL TABS w/ applicator	100 mg.	30	Pale Yellow	1.89	1.95	1.91	1.97	

* Sold in Minimum Quantity of 100 Bottles

Best Copy Available

Plaintiff's Exhibit 48

LIQUIDS

NATIONAL BRAND	PREMO EQUIVALENT PRODUCT	SIZE	PRICE PER BOTTLE: 1,440 OR MORE	576 TO 1,428	144 TO 348	24 TO 92	QUANTITY TO SHIP
BENADRYL ELIXIR	DIPHENHYDRAMINE HCl ELIXIR	4 oz.	.83	.89	.95	†	
BENADRYL ELIXIR	DIPHENHYDRAMINE HCl ELIXIR	pint	1.12	1.15	1.25	1.35	
BENADRYL ELIXIR	DIPHENHYDRAMINE HCl ELIXIR	gallon		4.45	4.72	5.09	
BENYLIN EXPECTORANT	DIPHENHYDRAMINE HCl EXPECTORANT	4 oz.	.90	.98	.98	1	
BENYLIN EXPECTORANT	DIPHENHYDRAMINE HCl EXPECTORANT	pint	1.15	1.20	1.30	1.42	
BENYLIN EXPECTORANT	DIPHENHYDRAMINE HCl EXPECTORANT	gallon		4.70	4.95	5.20	
DIMETANE EXPECTORANT	BROMPHENIRAMINE MALEATE EXPECTORANT	4 oz.	.59	.65	.75	†	
DIMETANE EXPECTORANT	BROMPHENIRAMINE MALEATE EXPECTORANT	pint	1.20	1.35	1.50	1.75	
DIMETANE EXPECTORANT	BROMPHENIRAMINE MALEATE EXPECTORANT	gallon	7.15	7.45	7.65	8.20	
DIMETAPP ELIXIR	PHENATAPP ELIXIR	4 oz.	.47	.45	.58	†	
DIMETAPP ELIXIR	PHENATAPP ELIXIR	pint	1.17	1.25	1.50	1.60	
DIMETAPP ELIXIR	PHENATAPP ELIXIR	gallon		5.15	5.45	6.00	
ELIXOPHYLLIN	THEOPHYLLINE ELIXIR	4 oz.	.43	.45	.50	†	
ELIXOPHYLLIN	THEOPHYLLINE ELIXIR	pint	.70	.75	.80	.94	
ELIXOPHYLLIN	THEOPHYLLINE ELIXIR	gallon		3.25	3.45	4.25	
KAY CIEL ELIXIR	POTASSIUM CHLORIDE, 10% SUGAR FREE, RED	4 oz.	.43	.45	.55	†	
KAY CIEL ELIXIR	POTASSIUM CHLORIDE, 10% SUGAR FREE, RED	pint	.71	.75	.85	.85	
KAY CIEL ELIXIR	POTASSIUM CHLORIDE, 10% SUGAR FREE, RED	gallon		3.20	3.50	4.25	
KAOCHLOR CONC. 20% LIQ.	POTASSIUM CHLORIDE, 20% SUGAR FREE, RED	4 oz.	.45	.50	.60	†	
KAOCHLOR CONC. 20% LIQ.	POTASSIUM CHLORIDE, 20% SUGAR FREE, RED	pint	.75	.80	.90	1.00	
KAOCHLOR CONC. 20% LIQ.	POTASSIUM CHLORIDE, 20% SUGAR FREE, RED	gallon		3.40	3.85	4.45	
KAOCHLOR 10% LIQUID	POTASSIUM CHLORIDE, 10% W/SUGAR, YELLOW	4 oz.	.52	.55	.65	†	
KAOCHLOR 10% LIQUID	POTASSIUM CHLORIDE, 10% W/SUGAR, YELLOW	pint	.74	.85	.94	1.10	
KAOCHLOR 10% LIQUID	POTASSIUM CHLORIDE, 10% W/SUGAR, YELLOW	gallon		3.45	3.90	4.35	
MAALOX SUSPENSION	ALU-MAG ANTACID SUSPENSION	12 oz.	.43	.46	.50	.60	
MAALOX SUSPENSION	ALU-MAG ANTACID SUSPENSION	gallon		3.20	3.50	4.25	
PHENERGAN EXPECT. PLAIN	PROMETHAZINE EXPECTORANT	4 oz.	.45	.50	.60	†	
PHENERGAN EXPECT. PLAIN	PROMETHAZINE EXPECTORANT	pint	1.00	1.10	1.25	1.40	
PHENERGAN EXPECT. PLAIN	PROMETHAZINE EXPECTORANT	gallon		6.15	6.40	6.70	
ROBITUSSIN EXPECTORANT	GLYCERYL GUAICOLATE EXPECTORANT	4 oz.	.44	.50	.55	†	
ROBITUSSIN EXPECTORANT	GLYCERYL GUAICOLATE EXPECTORANT	pint	1.12	1.15	1.25	1.40	
ROBITUSSIN EXPECTORANT	GLYCERYL GUAICOLATE EXPECTORANT	gallon		5.20	5.50	6.25	
SUDAFED SYRUP	PSEUDOEPHEDRINE HCl SYRUP	4 oz.	.59	.63	.70	†	
SUDAFED SYRUP	PSEUDOEPHEDRINE HCl SYRUP	pint	1.47	1.60	1.75	2.00	
SUDAFED SYRUP	PSEUDOEPHEDRINE HCl SYRUP	gallon		9.70	10.50	10.25	

† Sold in Minimum Quantity of 36 Bottles

CREAMS

NATIONAL BRAND	PREMO EQUIVALENT PRODUCT	STRENGTH	SIZE	PRICE PER TUBE: 1,440 OR MORE	576 TO 1,428	144 TO 432	72 TO 132	QUANTITY TO SHIP
KENALOG OR ARISTOCORT CREAM	ARISTALOG CREAM	0.025%	15 g.	.56	.59	.67	*	
KENALOG OR ARISTOCORT CREAM	ARISTALOG CREAM	0.025%	60 g.	1.41	1.48	1.58	1.81	
KENALOG OR ARISTOCORT CREAM	ARISTALOG CREAM	0.1%	15 g.	.85	.93	.98	*	
KENALOG OR ARISTOCORT CREAM	ARISTALOG CREAM	0.1%	60 g.	2.35	2.47	2.60	2.73	
KENALOG OR ARISTOCORT CREAM	ARISTALOG CREAM	0.5%	15 g.	2.03	2.14	2.25	*	
MYCOLOG CREAM	MYCO ARISTALOG CREAM		15 g.	1.52	1.60	1.68	*	
MYCOLOG CREAM	MYCO ARISTALOG CREAM		60 g.	4.66	5.12	5.36	5.60	
MYCOSTATIN CREAM	NYSTATIN CREAM	100,000 Units	15 g.	.88	.93	.98	*	

* Sold in Minimum Quantity of 144 Tubes

Plaintiff's Exhibit 48

THERMOMETERS BY OMEGA				
PERMARK THERMOMETERS . . . greater accuracy . . . less breakage . . . more economical				QUANTITY TO SHIP
TYPE	PACKAGING	PRICE		
ORAL, FAHRENHEIT, CYLINDRICAL	IN PEN TYPE PLASTIC HOLDER, INDIVIDUALLY BOXED, ONE DOZEN TO A CHIP	25 TO 100 DOZ.	$ 75/gross	
ORAL, FAHRENHEIT, STUBBY		101 DOZ. OR MORE	4.50/gross	
RECTAL, FAHRENHEIT, STUBBY				
ORAL, CENTIGRADE, CYLINDRICAL	IN PEN-TYPE PLASTIC HOLDER, INDIVIDUALLY BOXED, ONE DOZEN TO A CHIP.	25 TO 100 DOZ.	4.75/gross	
ORAL, CENTIGRADE, STUBBY		101 DOZ. OR MORE	4.50/gross	
RECTAL, CENTIGRADE, STUBBY				
ORAL, FAHRENHEIT, CYLINDRICAL	HOSPITAL PACK, 6 DOZ. TO A CONTAINER (IN INDIVIDUAL HYGEIA STRAWS)	5 TO 49 GROSS	47.00/gross	
ORAL, FAHRENHEIT, STUBBY		50 TO 99 GROSS	46.00/gross	
RECTAL, FAHRENHEIT, STUBBY		100 GROSS OR MORE	45.00/gross	
ORAL, CENTIGRADE, CYLINDRICAL	HOSPITAL PACK, 6 DOZ. TO A CONTAINER (IN INDIVIDUAL HYGEIA STRAWS)	5 TO 49 GROSS	47.00/gross	
ORAL, CENTIGRADE, STUBBY		50 TO 99 GROSS	46.00/gross	
RECTAL, CENTIGRADE, STUBBY		100 GROSS OR MORE	45.00/gross	
ORAL, FAHRENHEIT, CYLINDRICAL	BULK PACK, 100 PER BOX (IN FLUTED CORRUGATED ROLL)	$31.00 PER BOX; Minimum quantity - 150 Boxes		
ORAL, FAHRENHEIT, STUBBY				
RECTAL, FAHRENHEIT, STUBBY				
ORAL, CENTIGRADE, CYLINDRICAL	BULK PACK, 100 PER BOX (IN FLUTED CORRUGATED ROLL)	$31.00 PER BOX; Minimum quantity - 150 Boxes		
ORAL, CENTIGRADE, STUBBY				
RECTAL, CENTIGRADE, STUBBY				

Plaintiff's Exhibit 48

PRODUCT LIST

PREMO BRAND	TABLETS AND CAPSULES	NATIONAL BRAND
	ALGEMOL VELVETABS	GAVISCON TABLETS
	ALLOPURINOL TABLETS 100MG	ZYLOPRIM TABLETS
	ALLOPURINOL TABLETS 300MG	ZYLOPRIM TABLETS
*	CHLORDIAZEPOXIDE HCl CAPSULES 5MG	LIBRIUM CAPSULES
*	CHLORDIAZEPOXIDE HCl CAPSULES 10MG	LIBRIUM CAPSULES
*	CHLORDIAZEPOXIDE HCl CAPSULES 25MG	LIBRIUM CAPSULES
	CHLORDINIUM SEALETS	LIBRAX CAPSULES
	CHLORTHALIDONE TABLETS 50MG	HYGROTON TABLETS
	CHLORTHALIDONE TABLETS 100MG	HYGROTON TABLETS
	CHLORZOXAZONE WITH APAP TABLETS	PARAFON FORTE TABLETS
	CYCLANDELATE CAPSULES 200MG	CYCLOSPASMOL CAPSULES
	CYCLANDELATE CAPSULES 400MG	CYCLOSPASMOL CAPSULES
	DIPYRIDAMOLE TABLETS	PERSANTINE TABLETS
	DOXINE TABLETS	BENDECTINE TABLETS
	DYNOHIST S.A. TABLETS	ANTIHISTAMINE/DECONGESTANT
	HYDRALAZINE HCl TABLETS 25MG	APRESOLINE TABLETS
	HYDRALAZINE HCl TABLETS 50MG	APRESOLINE TABLETS
	HYDROXYZINE HCl TABLETS 10MG	ATARAX TABLETS
	HYDROXYZINE HCl TABLETS 25MG	ATARAX TABLETS
	HYDROXYZINE HCl TABLETS 50MG	ATARAX TABLETS
	HY-PAM CAPSULES 25MG	VISTARIL CAPSULES
	HY-PAM CAPSULES 50MG	VISTARIL CAPSULES
	IMIPRAMINE HCl TABLETS 10MG	TOFRANIL TABLETS
	IMIPRAMINE HCl TABLETS 25MG	TOFRANIL TABLETS
	IMIPRAMINE HCl TABLETS 50MG	TOFRANIL TABLETS
	INSULASE TABLETS (CHLORPROPAMIDE)	DIABINESE TABLETS
	ISOXSUPRINE HCl TABLETS 10MG	VASODILAN TABLETS
	ISOXSUPRINE HCl TABLETS 20MG	VASODILAN TABLETS
*	MEPROGESIC TABLETS	EQUAGESIC TABLETS
	MEPRO-HEX "200" TABLETS	PATHIBAMATE/MILPATH TABLETS
	MEPRO-HEX "400" TABLETS	PATHIBAMATE/MILPATH TABLETS
	NYSTATIN ORAL TABLETS	MYCOSTATIN ORAL TABLETS
	NYSTATIN VAGINAL TABLETS	MYCOSTATIN VAGINAL TABLETS
	PHENYLBUTAZONE ALKA CAPSULES	BUTAZOLIDIN ALKA CAPSULES
*	PROPOXYPHENE COMPOUND CAPSULES 65MG	DARVON COMPOUND CAPSULES
*	PROPOXYPHENE HCl CAPSULES 65MG	DARVON CAPSULES
	THEOPHEDRIZINE TABLETS	MARAX TABLETS
	TOLBUTAMIDE TABLETS	ORINASE TABLETS

*CIV Product - DEA Number Required

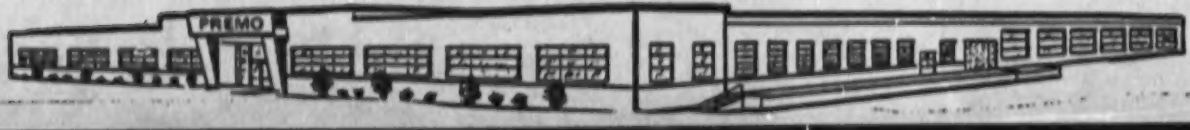
11/1/79

premo

"Pioneers in Generics"

Premo Pharmaceutical Laboratories, Inc.

111 LEUNING ST., SO. HACKENSACK, N.J. U.S.A. 07606 / (201) 343-5000



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Plaintiff's Exhibit 48

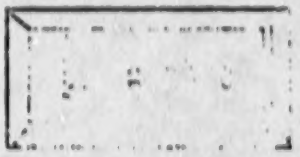
TABLETS AND CAPSULES

	100's	500's	1,000's
Algemol Velvetabs	1.65	7.70	-
Chlordinium Sealets	3.97	18.84	37.18
Chlorzoxazone with APAP	2.45	-	22.65
Cyclandelate Capsules 200mg.	1.43	-	11.33
Cyclandelate Capsuels 400mg.	2.32	10.66	20.32
Desihist Blue S.A. Tablets (New color)	3.96	18.75	36.34
Hydralazine HCl Tablets 25mg.	.79	-	5.30
Hydralazine HCl Tablets 50mg.	1.07	-	9.17
Imipramine HCl Tablets 25mg.	1.92	-	16.74
Isoxsuprine HCl Tablets 10mg.	3.03	-	27.28
Isoxsuprine HCl Tablets 20mg.	5.45	26.15	51.70
Phenatapp Extended Action Tablets	1.50	-	12.50
Nystatin Vaginal Tablets	Box of 15's 1.03		Box of 30's 1.83
Theophedrizine Tablets	2.15	-	18.80
Tolbutamide Tablets	4.60	22.00	43.00
Mepro-Hex Tablets 200	Please call for prices		
Mepro-Hex Tablets 400	Please call for prices		

Pr. 15 (Reading) added
Lot 51478

CREAMS

	15gm.	60gm.	80gm.	4oz.	1lb.	5lb.
Myco Triacet Cream	1.52	4.86	-	8.70	32.10	-
Nystatin Cream	.88	-	-	-	-	-
Triacet Cream .025%	.56	-	1.41	-	-	13.00
Triacet Cream .1%	.88	-	2.35	-	-	33.00
Triacet Cream .5%	2.03	-	-	-	-	-



"Pioneers in Generics"

Pharmaceutical Industries, Inc.
111 LUDWIG ST., SO. HACKENSACK, N.J. U.S.A. 07606 / (201) 343-5000

Plaintiff's Exhibit 48

CREAMS

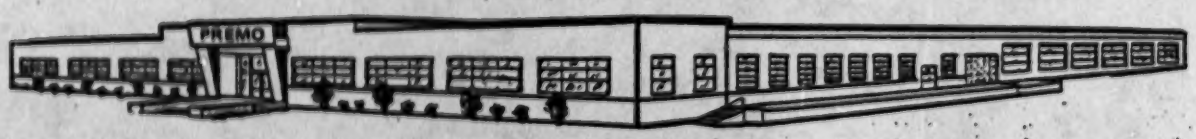
BETA-VAL CREAM 15GM.	BETAMETHASONE VALERATE CREAM
BETA-VAL CREAM 45GM.	BETAMETHASONE VALERATE CREAM
MYCO TRIACET CREAM.	MYCOLOG CREAM
NYSTATIN CREAM.	MYCOSTATIN CREAM
TRIACET CREAM .025%.	KENALOG AND ARISTACORT CREAM
TRIACET CREAM .1%.	KENALOG AND ARISTACORT CREAM
TRIACET CREAM .5%.	KENALOG AND ARISTACORT CREAM

premo

"Pioneers in Generics"

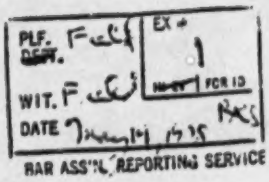
Premo Pharmaceutical Laboratories, Inc.

111 LEUNING ST., SO. HACKENSACK, N.J. U.S.A. 07606 / (201) 343-5000



PLAINTIFF'S EXHIBIT 49

Inwood Laboratories
INCORPORATED
300 PROSPECT STREET — INWOOD, N.Y. 11696
(212) 471-8000 — (516) 371-1155



"EXTRA DEAL OFFER"
3 FREE with 33
ON ALL SIZES

"SIXTY DAY SPECIALS"

Effective September 15 thru November 15, 1977

National Brand	GENERIC EQUIVALENT	Strength	Color	Unit Prices
DULCOLAX Tablets	BISACODYL Enteric-Coated Tablets	5 mg.	Yellow	100s - $ .60 1000s - 3.00
DIMETAPP EXTENTABS	BROMPHENTAPP T.D. Tablets		Lt. Blue	100s - 1.40 500s - 5.90 1000s - 11.00
CYCLOSPASMOL Caps	CYCLANDELATE Capsules	200 mg.	Lt. Blue	100s - 1.50 500s - 6.40 1000s - 12.00
CYCLOSPASMOL Caps	CYCLANDELATE Capsules	400 mg.	Red/Blue	100s - 2.20 500s - 9.90 1000s - 19.00
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE Tablets	25 mg.	Peach	100s - .60 1000s - 3.00
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE Tablets	50 mg.	Peach	100s - .70 1000s - 4.00
ISORDIL T.D. Tabs TEMBIDS	ISOSORBIDE DINITRATE T.D. Tablets	40 mg.	Yellow	100s - 1.90 500s - 8.40 1000s - 16.00
ROBAXIN	METHOCARBAMOL Tabs	500 mg.	White	100s - 1.90 500s - 8.40 1000s - 16.00
ROBAXIN	METHOCARBAMOL Tabs	750 mg.	White	100s - 2.80 500s - 12.90 1000s - 25.00
METICORTELONE	PREDNISOLONE Tablets	5 mg.	Peach	100s - .95 1000s - 6.50

No Free Goods Can Be Applied to this Item — Net Prices

LOMOTIL	(+) DIPHENOXYLATE HCl. with ATROPINE SULFATE Tablets	White	100s - $ 1.70 500s - 7.40 1000s - 14.00
	(+) DEA Number Required		

Please Request Our Complete Price List

TO QUALIFY ALL ORDERS MUST BE RECEIVED NO LATER THAN NOVEMBER 15, 1977

Plaintiff's Exhibit 49

Inwood Laboratories
INCORPORATED
300 PROSPECT STREET — INWOOD, N.Y. 11696
(212) 471-8000 — (516) 371-1155

PLF. DEF. EX. 2
WIT.
DATE
BAR ASS'N. REPORTING SERVICE

BULK PRICE LIST

PRESCRIPTION ITEMS

NATIONAL BRAND	GENERIC EQUIVALENT	Strength	Color	BULK ** PRICE per "M"
CYCLOSPASMOL Caps	CYCLANDELATE Caps	200 mg.	Lt. Blue	$ 12.00
CYCLOSPASMOL Caps	CYCLANDELATE Caps	400 mg.	Red/Blue	19.00
DIMETAPP EXTENTABS	BROMPHENTAPP T.D. Tabs		Lt. Blue	11.00
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE Tabs	25 mg.	Peach	(Prices on
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE Tabs	50 mg.	Peach	Request)
METANDREN	METHYLTESTOSTERONE Tabs	10 mg.	White	11.50
METICORTELONE	PREDNISOLONE Tabs	5 mg.	Peach	6.60
METICORTONE	PREDNISONE Tabs	5 mg.	White	5.70
NITRO-BID Caps	NITROGLYCERINE T.D. Caps	2.5 mg.	Purple/Clr.	1.00/100*
NITRO-BID Caps	NITROGLYCERINE T.D. Caps	6.5 mg.	Yellow/Blue	1.20/100*
NORGESIC	ORPHENADRINE W/APC Tabs		Yellow/Grn.	13.65
NORFLEX	ORPHENADRINE CIT. Tabs	100 mg.	White	14.70
PAVABID Caps	PAPAVERINE HCl. T.D. Caps	150 mg.	Brown/Clr.	11.75
PLEGINE	(+) PHENDIMETRAZINE TART. Tabs	35 mg.	Yellow	3.70
PLEGINE	(+) PHENDIMETRAZINE TART. Tabs	35 mg.	Pink	3.70
PLEGINE	(+) PHENDIMETRAZINE TART. Tabs	35 mg.	Green	3.70
PLEGINE	(+) PHENDIMETRAZINE TART. Tabs	35 mg.	Gray	3.70
ROBAXIN	METHOCARBAMOL Tabs	500 mg.	White	16.00
ROBAXIN	METHOCARBAMOL Tabs	750 mg.	White	25.00
ISORDIL T.D. Tabs TEMBIDS	ISOSORBIDE DINITRATE T.D. Tabs	40 mg.	Yellow	16.00
LOMOTIL	(+) DIPHENOXYLATE HCl. With ATROPINE SULFATE Tabs		White	16.00

(+) DEA Number Required

*supplied in 100s only

- -

TERMS OF SALE

PAYMENT: NET 30 DAYS
ARRANGEMENTS Available for
Customer's Label or
INWOOD Label.
SPECIAL FORMULATIONS
will be quoted upon request.

** ADDITIONAL Bottling & Labeling Charge:

100s ..... 30¢ each
500s ..... 40¢ each
1000s ..... 50¢ each

5/1/77

Plaintiff's Exhibit 49

Inwood Laboratories
INCORPORATED
300 PROSPECT STREET — INWOOD, N.Y. 11696
(212) 471-8000 — (516) 371-1155

BULK PRICE LIST

OVER-THE-COUNTER ITEMS

NATIONAL BRAND	GENERIC EQUIVALENT	Strength	Color	BULK ** PRICE Per "M"
ALLBEE With C Caps	B-COMPLEX With C Caps		Yellow/Grn.	$ 9.90
C-CHEWIES Tabs	CHEWABLE VITAMIN C Tabs	250 mg.	Orange	4.85
CONTAC COLD Caps	COLD Caps		Red/Clear	7.90
DULCOLAX Tablets	BISACODYL Enteric-Coated Tabs	5 mg.	Yellow	3.00
FEOSOL SPANSULES	FERROUS SULFATE T.D. Caps	150 mg.	Red/Clear	7.35
GEL-CAPS	GELATIN Capsules	10 gr.	Pink	6.85
ONE-A-DAY Tabs	BON-A-DAY Vitamin Tabs		Red	2.25
ONE-A-DAY W/IRON Tabs	BON-A-DAY With IRON Tabs		Yellow	2.50
TYLENOL Tablets	ACETAMINOPHEN Tablets	325 mg.	White	4.20
THERAGRAN-M Tabs	THERA-M VITAMIN Tabs		Maroon	8.90
VITAMIN B-12 Tablets	U.S.P.	50 mcg.	Pink	2.20
VITAMIN B-12 Tablets	U.S.P.	100 mcg.	Pink	2.90
VITAMIN C Tablets	ASCORBIC ACID Tablets	100 mg.	White	2.20
VITAMIN C Tablets	ASCORBIC ACID Tablets	250 mg.	White	3.95
VITAMIN C Tablets	ASCORBIC ACID Tablets	500 mg.	White	5.95

- - - - - - - - - - - - - - - - - -

TERMS OF SALE

PAYMENT: NET 30 DAYS
ARRANGEMENTS Available for
Customer's Label or
INWOOD Label.
SPECIAL FORMULATIONS
will be quoted upon request.

**ADDITIONAL Bottling & Labeling Charge:

100s ..... 30¢ each
500s ..... 40¢ each
1000s ..... 50¢ each

5/1/77

Plaintiff's Exhibit 49

Inwood Laboratories
INCORPORATED
300 PROSPECT STREET — INWOOD, N.Y. 11696
(212) 471-8000 — (516) 371-1155

SEYMOUR FIELD
Vice President — Operations

PLF. DEFT. EX # 3
WIT.
DATE
BAR ASS'N. REPORTING SERVICE

BULK PRICE LIST

PRESCRIPTION ITEMS

NATIONAL BRAND	GENERIC EQUIVALENT	Strength	Color	BULK ** PRICE PER "M"
CYCLOSPASMOL Caps	CYCLANDELATE Caps	200 mg.	Lt. Blue	$15.25
CYCLOSPASMOL Caps	CYCLANDELATE Caps	400 mg.	Red/Blue	20.50
DIMETAPP EXTENTABS	BROMPHENTAPP T.D. Tabs		Lt. Blue	11.50
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE	25 mg.	Peach	2.00
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE	50 mg.	Peach	3.00
METICORTELONE	PREDNISOLONE Tabs	5 mg.	Peach	6.85
METICORTONE	PREDNISONE Tabs	5 mg.	White	5.85
NITRO-BID Caps.	NITROGLYCERINE T.D. Caps	2.5 mg.	Purple/Clr.	1.00/C *
NITRO-BID Caps	NITROGLYCERINE T.D. Caps	6.5 mg.	Yellow/Blue	1.20/C *
NORGESIC	ORPHENGESIC Tabs		Yellow/Grn.	13.65
NORFLEX	ORPHENADRINE CIT. Tabs	100 mg.	White	14.70
PAVABID Caps	PAPAVERINE HCl. T.D. Caps	150 mg.	Brown/Clr.	11.75
PLEGINE	PHENDIMETRAZINE TART. Tabs	35mg.	Yellow	3.70
"	"	"	Pink	3.70
"	"	"	Green	3.70
"	"	"	Gray	3.70
ROBAXIN	METHOCARBAMOL Tabs	500 mg.	White	16.50
ROBAXIN	METHOCARBAMOL Tabs	750 mg.	White	25.50

OVER-THE-COUNTER-ITEMS

ALLBEE W/C Caps	B-COMPLEX W/C Caps		Yellow/Grn.	8.90
C-CHEWIES Tablets	CHEWABLE VITAMIN C Tabs	100 mg.	Orange	2.65
C-CHEWIES Tablets	CHEWABLE VITAMIN C Tabs	250 mg.	Orange	4.85
CONTAC COLD Capsules	COLD Capsules		Red/Clear	7.90
DULCOLAX Tablets	BISACODYL Ent. Coated Tabs	5 mg.	Yellow	3.00
FEOSOL SPANSULES	FERROUS SULFATE T.D. Caps	150 mg.	Red/Clear	7.35
GEL-CAPS	GELATIN Capsules	10 gr.	Pink	6.85
ONE-A-DAY Tablets	BON-A-DAY Vitamin Tablets		Red	2.10
ONE-A-DAY w/IRON Tabs	BON-A-DAY w/IRON Tabs		Yellow	2.25
TYLENOL Tablets	ACETAMINOPHEN Tablets	325 mg.	White	4.20
THERAGRAN Tablets	THERA VITAMINS		Red	8.40
THERAGRAN-M Tablets	THERA-M VITAMINS		Maroon	8.90

* supplied in 100s only

(continued)

** See Page. #2

Inwood Laboratories
INCORPORATED
300 PROSPECT STREET — INWOOD, N.Y. 11696
(212) 471-8000 — (516) 371-1155

SEYMOUR FIELD
Vice President — Operations

OVER-THE-COUNTER ITEMS

NATIONAL BRAND	GENERIC EQUIVALENT	Strength	Color	BULK PRICE PER "M"
VITAMIN B-1 Tablets	U.S.P.	50 mg.	White	3.15
VITAMIN B-1 Tablets	U.S.P.	100 mg.	White	4.70
VITAMIN B-12 Tablets	U.S.P.	50 mcg.	Pink	2.20
VITAMIN B-12 Tablets	U.S.P.	100 mcg.	Pink	2.90
VITAMIN C Tablets	ASCORBIC ACID Tablets	100 mg.	White	2.00
VITAMIN C Tablets	ASCORBIC ACID Tablets	250 mg.	White	3.75
VITAMIN C Tablets	ASCORBIC ACID Tablets	500 mg.	White	5.75

TERMS OF SALE

PAYMENT: NET 30 DAYS

ARRANGEMENTS Available for Customers Label
Or INWOOD Label

SPECIAL FORMULATIONS will be quoted upon request.

#ADDITIONAL Bottling & Labeling Charg

100s ..... 30¢ each
500s ..... 40¢ each
1000s ..... 50¢ each

Plaintiff's Exhibit 49

Inwood Laboratories
INCORPORATED
300 PROSPECT STREET—INWOOD, N.Y. 11696

NATIONAL BRAND	GENERIC EQUIVALENT	STRENGTH	COLOR	UNIT	PRICES
DIMETAPP EXTENTABS	BROMPHENTAPP T.D. TABLETS		Lt. Blue	100s	$1.40
				500s	5.90
				1000s	11.00
CYCLOSPASMOL CAPSULES	CYCLANDELATE CAPSULES	200 mg.	Lt. Blue	100s	1.40
				500s	5.90
				1000s	11.00
CYCLOSPASMOL CAPSULES	CYCLANDELATE CAPSULES	400 mg.	Red/Blue	100s	2.10
				500s	9.60
				1000s	18.75
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE TABLETS	25 mg.	Peach	100s	.60
	Licensed under Patent #3163645			1000s	3.00
HYDRO-DIURIL	HYDROCHLOROTHIAZIDE TABLETS	50 mg.	Peach	100s	.70
	Licensed under Patent #3153645			1000s	3.75
ISORDIL T.D. TABLETS TEMBIDS	ISOSORBIDE DINITRATE T.D. TABLETS	40 mg.	Yellow	100s	1.80
				500s	7.90
				1000s	15.00
ROBAXIN	METHOCARBAMOL TABLETS	500 mg.	White	100s	1.60
				500s	7.90
				1000s	15.00
ROBAXIN	METHOCARBAMOL TABLETS	750 mg.	White	100s	2.95
				500s	12.50
				1000s	24.00
METICORTELONE	PREDNISOLONE TABLETS	5 mg.	Peach	100s	1.30
	Licensed under Patent #3134716			1000s	6.00
METICORTONE	PREDNISONE TABLETS	5 mg.	White	100s	1.15
	Licensed under Patent #3134716			1000s	7.00

NO FREE GOODS CAN BE APPLIED TO THIS EXTRA OFFER

NATIONAL BRAND	GENERIC EQUIVALENT	STRENGTH	COLOR
NITRO-BID CAPSULES	NITROGLYCERINE T.D. CAPSULES	2.5 mg.	Purple/Clr.
	MINIMUM ORDER 250 x 100 and over .90 Per Bottle		
	1000 x 100 and over .75 Per Bottle		
NITRO-BID CAPSULES	NITROGLYCERINE T.D. CAPSULES	6.5 mg.	Yellow/Blue
	MINIMUM ORDER 250 x 100 and over 1.05 Per Bottle		
	1000 x 100 and over .90 Per Bottle		

TO QUALIFY ORDERS MUST BE POSTMARKED NO LATER THAN JUNE 15th, 1978
OFFER IS AND SUBJECT TO PRICE AND AVAILABILITY

Plaintiff's Exhibit 49

NO FREE GOODS PERMITTED

D.E.A. NUMBER REQUIRED WHEN ORDERING

NATIONAL BRAND	GENERIC EQUIVALENT	STRENGTH	COLOR	UNIT PRICES	
FIORINAL TABLETS	BUTALBITAL TABLETS with A.P.C.	—	White	100s	$1.05
				500s	3.90
				1000s	7.50
LOMOTIL	DIPHENOXYLATE HCL with Atropine Sulfate Tablets	—	White	100s	1.10
				500s	4.50
				1000s	8.00
PLEGINE	PHENDIMETRAZINE TARTRATE Can be supplied in Yellow, Pink, Green, Gray	35 mg.		1000s	3.90

BULK OVER-THE-COUNTER ITEMS

NATIONAL BRAND	GENERIC EQUIVALENT	STRENGTH	COLOR	**BULK PRICE Per "M"
ALLBEE With C Caps	B-COMPLEX With C Caps	—	Yellow/Grn.	$9.90
CONTAC COLD CAPSULES	COLD CAPSULES	—	Red/Clr.	7.90
FEOSOL SPANSULES	FERROUS SULFATE T.D. CAPSULES	150 mg.	Red/Clr.	6.95
GEL-CAPS	GELATIN CAPSULES	10 gr.	Pink	6.85
TYLENOL TABLETS	ACETAMINOPHEN TABLETS	325 mg.	White	4.20
VITAMIN C TABLETS	ASCORBIC ACID TABLETS	250 mg.	White	3.75
VITAMIN C TABLETS	ASCORBIC ACID TABLETS	500 mg.	White	6.45

TERMS OF SALE

PAYMENT: NET 30 DAYS
ARRANGEMENTS Available for Customer's Label or INWOOD Label.
SPECIAL FORMULATIONS will be quoted upon request.

**ADDITIONAL Bottling & Labeling Charge:

100s ..... 30c each
500s ..... 40c each
1000s ..... 50c each

Guaranteed conformity to F.D.A.-U.S.P. and N.F. standards

Complete bioavailability where required • Quality generic products

Competitive price structure • Dedicated service

Finest laboratory control available—full assay report issued with each batch

For information and orders, call: (212) 471-8000 (516) 371-1155

10,000

616a
Plaintiff's Exhibit 49

Inwood Laboratories
INCORPORATED
300 PROSPECT STREET — INWOOD, N.Y. 11696
(212) 471-8000 — (516) 371-1155

Sy. Field

PLF. DEFT. EX # 17 IN EV FOR ID
WIT.
DATE Mar. 19 1978
BAR ASS'N. REPORTING SERVICE

FALL - WINTER PROMOTIONS

1976 - 1977

. . . . . .

GENERICS

VITAMINS

O.T.C. PRODUCTS

SPECIAL NET PRICES

MINIMUM SHIPPING ORDER: $35.00 Net

NART only
Bulk

Exhibit L- MC

A DIVISION OF FOREST LABORATORIES, INC.

Plaintiff's Exhibit 49

Quantity	SIZE	GENERIC PRODUCTS	SPECIAL NET PRICE
	100	APAP Tablets (comparable to Tylenol)	$ .6
	1000	APAP Tablets	5.2
	100	Bon-O-Lax Tablets (comparable to Dulcolax)	.7
	1000	Bon-O-Lax Tablets (Bisacodyl Tablets, U.S.P., 5 mg. enteric-coated)	5.0
	100	Bromphentapp T.D. Tablets (comparable to	1.7
	500	Bromphentapp T.D. Tablets Dimetapp Extentabs)	8.0
~~19.00~~ 11.00	1000 *	Bromphentapp T.D. Tablets	15.0
	1000	Chlorpheniramine Maleate Tablets, 4 mg. (comparable to Chlor-Trimeton)	1.75
	100	Cyclandelate Capsules, 200 mg. (comparable to	2.50
	500	Cyclandelate Capsules, 200 mg. Cyclospasmol Capsules)	12.00
~~25~~ 17.00	1000 *	Cyclandelate Capsules, 200 mg.	23.00
	100	Cyclandelate Capsules, 400 mg. (comparable to	4.50
	500	Cyclandelate Capsules, 400 mg. Cyclospasmol Capsules)	21.50
~~[illegible]~~ 19.00	1000	Cyclandelate Capsules, 400 mg.	40.00
	100	Ferrous Sulfate T.D. Capsules, 150 mg. (comparable to	1.00
	1000	Ferrous Sulfate T.D. Capsules, 150 mg. Feosol Spansules)	9.00
	100	Gelatin Capsules, 10 grs., Pink	1.00
	100	Hydrochlorothiazide Tablets, U.S.P. 25 mg. & 50 mg. 2.50 M 4.30 M	Prices c
	1000	(comparable to Hydrodiuril) 2.00 Peach	Request
		Isosorbide TD tab-40 mg 16.00	
	100	Methocarbamol Tablets, 500 mg. (comparable to	3.20
	500	Methocarbamol Tablets, 500 mg. Robaxin Tablets)	15.00
.50	1000	Methocarbamol Tablets, 500 mg.	29.00
	100	Methocarbamol Tablets, 750 mg. (comparable to	4.50
	500	Methocarbamol Tablets, 750 mg. Robaxin Tablets)	20.00
.50	1000	Methocarbamol Tablets, 750 mg.	38.00
	100	Methyltestosterone Tablets, 10 mg. (comparable to	1.90
11.50	1000	Methyltestosterone Tablets, 10 mg. Metandren)	16.00
	100	Methyltestosterone Tablets, 25 mg. (comparable to	3.80
	1000	Methyltestosterone Tablets, 25 mg. Metandren)	36.00
.00	100	Nitroglycerin Capsules 2.5 mg. T.D., Lav. & Clear	1.35
.20	100 *	Nitroglycerin Capsules 6.5 mg. T.D., Blue & Orange (comparable to Nitro-Bid)	1.50
	100	Orphenadrine Citrate Tablets, 100 mg. (comparable to	3.50
.70	500	Orphenadrine Citrate Tablets, 100 mg. Norflex)	16.50
	1000	Orphenadrine Citrate Tablets, 100 mg.	31.00

Plaintiff's Exhibit 49

Quantity	SIZE	GENERIC PRODUCTS	SPECIAL NET PRICES
	100	Orphengesic Tablets (comparable to Norgesic Tablets)	$ 2.50
	500	Orphengesic Tablets	11.50
3.60	1000	Orphengesic Tablets	20.00
	100	Papaverine Hydrochloride Capsules, U.S.P., T.D. 150 mg., Brown & Clear	2.00
12.00	1000 *	Papaverine Hydrochloride Capsules, U.S.P., T.D. 150 mg., Brown & Clear (comparable to Pavabid)	14.50
	1000	* Phendimetrazine Bitartrate Tablets, 35 mg., Yellow, Pink,	7.50
	5000	* Phendimetrazine Bitartrate Tablets, " Green & Gray (comparable to Plegine)	36.50
	100	Prednisolone Tablets, 5 mg. (comparable to	1.10
6.60	1000 *	Prednisolone Tablets, 5 mg. Meticortelone)	8.25
	100 *	Prednisone Tablets, 5 mg. (comparable to	1.00
5.00	1000	Prednisone Tablets, 5 mg. Meticorten)	7.50
	100	Tetracycline Hydrochloride Capsules, U.S.P., 250 mg., Yellow & Orange	1.50
	1000 * 10.00	Tetracycline Hydrochloride Capsules, U.S.P., 250 mg., Yellow & Orange	11.25

* D.E.A. No. Required

SPECIAL OFFER

4 oz.	Exo-Kol Cough Syrup - Adult - New Formula	60¢ Net Each
4 oz.	Exo-Kol Cough Cyrup - Pediatric - New Formula	60¢ Net Each
4 oz.	Elixir Terpin Hydrate with D.M., N.F. (Subject to prior sale and availability) Packed: 2 doz. to a shipping carton per item)	60¢ Net Each

Quantity	SIZE	VITAMIN PRODUCTS	NET PRICES
	100	Ascorbic Acid Tablets, 100 mg.	$ .40
	100	Ascorbic Acid Tablets, 250 mg.	.60
	250	Ascorbic Acid Tablets, 250 mg.	1.25
	1000	Ascorbic Acid Tablets, 250 mg.	4.50
	100	Ascorbic Acid Tablets, 500 mg.	.95
	250	Ascorbic Acid Tablets, 500 mg.	2.10
	1000	Ascorbic Acid Tablets, 500 mg.	8.00
	100	Ascorbic Acid Chewable Tablets, 100 mg.	.43
	1000	Ascorbic Acid Chewable Tablets, 100 mg.	4.00
	100	Ascorbic Acid Chewable Tablets, 250 mg.	.85
	1000	Ascorbic Acid Chewable Tablets, 250 mg.	6.50
	100	Ascorbic Acid Chewable Tablets, 500 mg.	1.50

PLAINTIFF'S EXHIBIT 50

DARBY DRUG CO., INC.

100 Banks Ave.
Rockville Centre, N.Y. 11570

WINTER 1977

BRANDED GENERICS FROM DARBY

NEW EXPANDED ISSUE

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VITAMIN B-12

Crystalline 1000 mcg. CC

	10	50
300-2040 10cc vials	4.50	21.25
300-2060 30cc vials	5.60	26.90

CHLORDIAZEPOXIDE HCL.®

(Similar to Librium)

5 mg. Caps (Yellow & Green)	10 mg. Caps (Black & Green)	25 mg. Caps (White & Green)
003-4870 100 — 1.45	003-4880 100 — 1.80	003-4890 100 — 2.30
003-4872 500 — 6.40	003-4882 500 — 7.25	003-4892 500 — 10.25
003-4872 2x500 — 12.45	003-4885 1M — 13.45	003-4892 2x500 — 18.95

TETRACYCLINE HCL.

F.D.A. Certified U.S.P.

250 mg. Caps (Orange & Yellow)	500 mg. Caps (Black & Yellow)
310-1825 1M -11.75	310-1870 100 -2.70
310-1825 5x 1M -58.25	310-1875 1M -22.80

AMPICILLIN TRIHYDRATE

F.D.A. Certified

250 mg. Caps	500 mg. Caps
310-0010 100 -4.70	310-0016 100 - 9.30
310-0015 500 -22.85	310-0018 500 -45.50
310-0013 1M -45.20	310-0019 2x 500 -90.50

PROPOXYPHENE COMPOUND-65

(Similar to Darvon Compound-65)

004-3830 100 — 1.95
004-3832 500 — 7.45
004-3834 1M — 14.25

ERYTHROMYCIN STEARATE TABS

250 mg.
310-0250 100 — 5.55
310-0255 500 — 26.85

PAVAGEN

(Papaverine HCl)
150 mg. T.D. Caps

004-1248 100 — 1.95
004-1249 500 — 7.95
004-1247 1M — 14.95

DIPHENATOL®

Tabs
(Similar to Lomotil)

003-7630 100 — 2.75
003-7635 500 — 11.95

PLAINTIFF'S EXHIBIT 50

STERILE DISPOSABLE SYRINGES

MANUFACTURED IN U.S.A. 5cc w/NEEDLE

SIZES AVAILABLE

321-1040	25 x ⅝	321-1030	22 x 1¼	321-1010	21 x 1
321-1035	23 x 1	321-1025	22 x 1½	321-1005	20 x 1½
321-1020	22 x 1	321-1015	21 x 1½	321-1000	20 x 1

100 6.90 1000 65.70

Plaintiff's Exhibit 50

IMPORTANT
Please add STOCK No. when ordering.

-84e-

Tablets/Capsules

		1M	5x1M
Cold Tabs #2 with DMH (Rose)	Phenylpropanolamine Hcl. 25 mg. Chlorpheniramine 2 mg. Pyrilamine Maleate 10 mg. Terpin Hydrate 2½ gr. APAP 5 gr. Dextromethorphan HBr 7½ mg.	15.50	75.25
003-5010			
Cold Tabs Flavored (Children's) (Yellow)	Salicylamide ¼ gr. Acetophenetidin ½ gr. Camphor Monobrs. ⅛ gr. Atropine Sulf. 1/322 gr. Phenolphthalein 1/10 gr.	2.75	12.90
003-5100			
Cold Capsules—Mild (Yellow/Blue)	Acetylsalicylic Acid 3½ gr. Acetophenetidin 2½ gr. Pyrilamine Mal. 10 mg. Caffeine ½ gr.	8.75	42.50
003-5040			
Cold Capsules—Medium (Yellow/Purple)	Salicylamide 2½ gr. Acetophenetidin 2½ gr. Caffeine ½ gr. Pyrilamine Mal. 25 mg.	11.50	56.50
003-5060			
Cold Capsules—Forte (Brown/White)	Acetylsalicylic Acid 2½ gr. Acetophenetidin 1½ gr. Quinine Sulfate ½ gr. Atropine Sulfate 1/1000 gr. Camphor ½ gr. Podophyllin 1/60 gr. Aloin 1/10 gr.	10.90	53.20
003-5080			
Conjugated Estrogens U.S.P.			
003-5181	0.625 mg. Tabs (Maroon) 003-5180 (100—1.85)	16.95	
003-5221	1.25 mg. Tabs (Yellow) 003-5220 (100—3.15)	24.50	
003-5260	2.50 mg. Tabs (Purple) 003-5260 (100—5.40)	37.50	
Cortisone Tablets			
003-5300	25 mg. (White) (100—3.75)	34.90	
Cough Wafers/Mentholated	Benzocaine ¼ gr. — Licorice P.E. 1/16 gr. Oil of Anise, Eucalyptol and Menthol	2.75	12.95
003-5340			
CYCLANDELATE (Similar to Cyclospasmol)			
003-5315	200 mg. Caps (Blue) 003-5310 (100—1.85)	14.65	
003-5290	400 mg. Caps (100—3.45)		
CYTOMINE® Tabs (Similar to Cytomel)			
003-5338	25 mcg. (White) 003-5330 (100—1.10)	7.45	
003-5357	50 mcg. (White) 003-5355 (100—1.15)	8.95	

ONE OF AMERICA'S MOST POPULAR GENERIC FORMULAS

		1M	5x1M
DARLITE® (Capsule Shaped Tabs) (S.C. Brown)	D 400 un. A 5,500 un. C 60 mg. B1 3.5 mg. B2 2.4 mg. B6 0.8 mg. B12 1.5 mcg. E 3 u.s. Cal. Pan. 3.5 mg. Niacinamide 12 mg. Pot. Sulfate 6 mg. Zinc Sulfate 0.2 mg. Dried Yeast 10 mg. Wheat Germ Oil 10 mg. Biotin 3 mcg. Choline Bitar. 5 mg. Dical. Phos. 110 mg. Inositol 5 mg. Phosphorous 65 mg. Ferrous Sulf. 12 mg. Iodine (Pot. Iodide) 0.13 mg. Copper Sulfate 0.25 mg. Manganese Sulf. 0.25 mg. Magnesium Sulf. 5 mg. Para-Amino-Benzoic Acid 5 mg.	6.50	31.00
003-5541			
	Also Available 003-5540 100—.85 10x100—8.00		

		1M	5x1M
DECONGEST Tabs (White) (Similar to Dristan) (100—.95)	Phenylephrine Hcl. 5 mg. — Phenindamine Tartrate 10 mg. — Aspirin, Caffeine — Alum. Hydroxide — Magnesium Carb. Co-dried gel.	8.75	
003-5710			
DECONGESTIVE T.D. Caps 003-5720 (250—5.05)	Chlorpheniramine Maleate 8 mg. Phenylephrine Hcl. 20 mg. Methscopolamine Nitrate 2.5 mg.	19.50	
003-5721			
DEGENEX Caps (Similar to Ornex) 003-5740 (100—1.65)	Acetaminophen 325 mg. Phenylpropanolamine Hcl. 18 mg.	12.95	
003-5745			
Dehydrocholic Acid Tabs			
003-5760	3¼ gr. (White)	27.85	
003-5780	3¼ gr. w/Belladonna Alk. (White)	28.90	
DEXAMETHASONE			
003-5820	0.75 mg. Tabs (Green) (100—3.80)	36.30	
003-5840	1.5 mg. Tabs (Pink) (100—4.15)		

C-D

GENERIC GUIDE Section

DARBY

NAME BRAND

CORTONE
25 MG. TABS
(Cortisone Acetate)
Merck
173-1210 100—11.40

CRYSTODIGIN
TABS
Lilly
159-2155 0.1 MG.... 500— 4.15
159-2160 0.1 MG.... 5000—32.50
159-2250 0.2 MG.... 500— 6.20

CYCLOSPASMOL
200 MG. CAPS
Ives
144-0200 100— 8.40
144-0238 1M—78.45

CYTOMEL
(Sod. Liothyronine)
S.K.F.
25 MCG. TABS
250-2100 100— 2.70
250-2105 1M—25.50
50 MCG. TABS
250-2115 100— 4.10

"BRANDED GENERICS" by DARBY

ORDER BY NUMBER PLEASE

CORTISONE ACETATE
25 MG. TABS
Darby
003-5300 100— 3.75
003-5305 10x100—34.90

DIGITOXIN
TABS
Darby
003-7300 0.1 MG. 1M— 2.20
003-7301 0.1 MG. 1x5M—10.15
003-7320 0.2 MG. 1M— 2.60
003-7321 0.2 MG. 1x5M—11.75

CYCLANDELATE
200 MG. CAPS
Darby
003-5310 100— 1.85
003-5315 1M—14.65

CYTOMINE™
(Sod. Liothyronine)
Darby
25 MCG. TABS
003-5330 100—1.10
003-5335 1M—7.45
50 MCG. TABS
003-5336 100—1.15
003-5337 1M—8.95

PROPOXYPHENE
w/APAP Darby
Each Capsule Shows:
Tab Contains:
Propoxyphene HCl—32 mg.
Acetaminophen—325 mg.
004-3980 100—2.50
004-3985 500—10.95

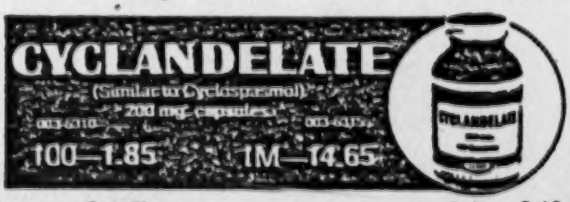
PROPOXYPHENE
w/APAP Darby
Each Capsule Shows:
Tab Contains:
Propoxyphene HCl—32 mg.
Acetaminophen—325 mg.
004-3870 100—4.15
004-3875 500—18.95

IMPORTANT! Please add Stock No. when ordering

C (Continued)

		Size	Price
	Cortisporin		
122-1700	Oint. ½ oz.	1—	3.00
122-1810	Otic	10cc—	3.00
122-1900	Ophth. Oint. 1/8 oz.	1—	1.50
122-2000	Ophth. Susp.	5cc—	2.10
172-1210	Cortone 25 mg. tabs	100—	11.40
172-1220	Cortone 25 mg./cc. (10—50.60)	20cc—	5.20
132-1900	Cort-Quin Creme ½%—½ oz.	1—	2.20
207-0400	Cortril Oint. ½oz.	1—	1.50
207-0480	Coryban-D caps	24—	1.00
230-1600	Co-Salt	8oz—	2.65
168-3730	Cosanyl-DM Cough Syrup	1pt.—	4.85
184-0300	Cotazym caps	100—	5.95
184-0410	Cotazym-B	60—	5.25
328-6380	Cotton Swabs Sterile J&J	175—	1.10
164-2430	Co-Tylenol tabs.	30—	1.05

	COUMADIN (Warfarin Sod.)		
138-0100	2mg. (1M—45.75)	100—	4.85
138-0200	2.5 mg. (1M—45.75)	100—	4.85
138-0500	5 mg. (1M—50.25)	100—	5.40
138-0700	7.5 mg	100—	6.55
138-0800	10 mg. (1M—72.60)	100—	7.80
242-0600	Creamalin tabs.	200—	2.95
179-2430	Crest Toothpaste Family Size	1—	1.20
179-2438	Crest Toothpaste Mint Flav	1—	1.20
187-2438	Cruex Spray Powder	4oz—	1.60
187-2440	Cruex Spray Powder	12oz—	3.35
	CRYSTICILLIN		
222-0325	300 A.S. 10cc. (50—37.20)	10—	7.90
222-0350	600 A.S. 12cc. (50—72.60)	10—	15.20
	CRYSTODIGIN		
158-2150	0.05 mg	500—	2.55
158-2188	0.1 mg. (5M—32.50)	500—	4.15
158-2200	0.15 mg.	500—	5.45
158-2250	0.2 mg.	500—	6.20
131-2440	Cuprex	3oz—	1.95
172-1300	Cuprimine 250 mg. caps	50—	9.80
254-2480	Cuticura Soap Bath Bars	3—	1.65
259-1800	Cyclogesterin Oil	5cc—	5.75
104-2500	Cyclogyl 0.5%	15ml—	4.90
104-2600	Cyclogyl 1.0%	15ml—	5.65
104-0380	Cyclomydril Ophthalmic Sol.	7.5cc—	3.15
	CYCLOSPASMOL (Cyclandelate)		
144-0100	100 mg. tabs. (500—19.30)	100—	4.20
144-0200	200 mg. caps. (500—39.90)	100—	8.40
144-0288	200 mg. caps	1M—	78.45



158-2300	Cytellin.	1pt.—	6.10
118-1100	Cytoferin tabs	100—	3.00
220-2000	Cytomel 5 mcg.	100—	1.80
220-2100	Cytomel 25 mcg. (1M—25.60)	100—	2.70
220-2118	Cytomel 50 mcg.	100—	4.10
168-0725	Cytoxan 25 mg tabs	100—	11.15
168-0750	Cytoxan 50 mg. tabs.	100—	20.50

D

		Size	Price
140-0460	D.B.I. 25 mg. tabs. (1M—52.20)	100—	5.40
140-0480	DBI T.D.C. 50 mg. (1M—116.50)	100—	11.95
208-1500	D.H.E. 45 1cc amps	20—	16.70
174-1170	Dactil w/Pheno tabs	50—	3.25
180-1001	Dainite-KI tabs. (500—45.20)	100—	9.80
200-0710	Daimane 15 mg. caps.	100—	6.45
200-0715		500—	30.90
200-0730	Daimane 30 mg. caps.	100—	7.70
200-0735		500—	37.30
243-0900	Danocrine 200 mg caps.	100—	97.50
136-0072	Dantrium 25 mg. caps.	100—	9.25
136-0082	Dantrium 100 mg. caps	100—	17.85
186-1010	Dara Shampoo	1pt.—	2.70
173-1700	Daranide 50 mg. tabs	100—	7.30
122-3100	Daraprim tabs. (1M—12.90)	100—	1.45
220-2300	Darbid 5 mg. tabs (Isopropamide)	50—	3.90
162-0360	Daricon 10 mg. tabs. (500—52.60)	60—	5.45
162-0370	Daricon-PB tabs	100—	9.30
166-2340	Darvocet-N tabs. (500—20.90)	100—	4.25
166-2347	Darvocet-N 100. (500—38.90)	100—	7.85
166-2360	Darvon 32 mg. (500—16.70)	100—	3.80
166-2450	Darvon Comp-32. (500—17.90)	100—	3.80
166-2400	Darvon 65 mg. (500—31.45)	100—	6.80
166-2500	Darvon Comp-65. (500—31.70)	100—	6.90
166-2310	Darvon ASA caps. (500—33.70)	100—	6.85
166-2310	Darvon-N tabs. (500—35.75)	100—	7.25
166-2329	Darvon-N Susp. 50 mg./5cc	1pt.—	5.40
166-2325	Darvon-N w/A.S.A. (500—35.50)	100—	7.35
113-2900	Detril tabs	100—	1.45
132-1980	Dexolin caps 10 mg.	100—	10.90
132-1990	Dexolin caps 25 mg.	100—	16.60
132-1970	Dexolin caps 50 mg.	100—	21.90
103-0800	Dayalets	250—	7.65
103-0900	Dayalets w/Iron tabs. (250—8.25)	100—	3.50
186-0100	Deaner 25 mg. tabs.	100—	6.60
186-0300	Deaner 100 mg. tabs.	50—	6.60
	DECADRON (Dexamethasone)		
172-1900	4 mg./cc. (25cc—26.65)	5cc—	5.50
172-2300	4 mg./cc w/Xylocaine	5cc—	5.50
172-2110	L.A. Suspension	5cc—	8.90
172-1650	0.5 mg. tabs	100—	11.20
172-2000	0.75 mg. tabs	100—	13.70
172-1920	4 mg. tabs	50—	21.40
172-2100	Elixir 100cc	1—	3.45
172-2125	Ophth. Oint. 0.05% 3.5 gm.	1—	1.15
172-2150	Ophth. Sol. 0.1% 2.5cc	1—	1.60
172-2175	Respihaler Aerosol	1—	5.15
172-2200	Turbinaire 12.6 gm.	1—	5.45
172-2250	Topical Cream 0.1%	15gm—	2.15
172-1910	24 mg/cc	5cc—	23.75
184-0600	Deca-Durabolin Box 4 x 1cc	1—	17.95
184-0800	Deca-Durabolin 50 mg./cc.	2cc—	8.20
184-0910	Deca-Durabolin 100 mg./cc	2cc—	14.40
172-2400	Decagesic tabs	100—	7.10
172-2480	Decaspray Topical Aerosol	1—	2.72
132-2030	Decholin Amps 5cc.	20—	14.85
132-2050	Decholin tabs. (500—31.70)	100—	6.55

PLAINTIFF'S EXHIBIT 51

Sherry 1977 MEDICAL/SURGICAL CATALOG Fall

AMITRIPTYLINE HCL

Comparable to Elavil

10 mg. Blue Film Coated

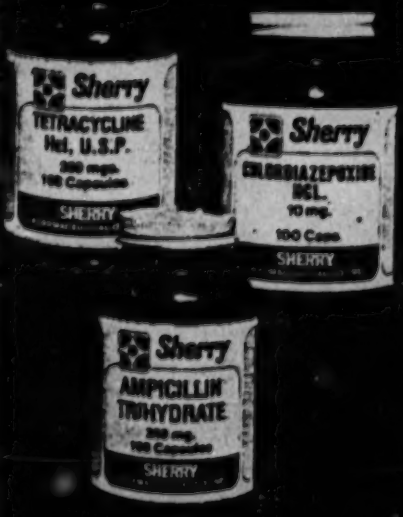
003-0710	1x100	2.60
003-0715	1x1000	20.75

25 mg. Yellow Film Coated

003-0720	1x100	3.45
003-0725	1x1000	30.55

50 mg. Beige F.C.

003-0730	1x100	5.35



NEW-INFLUENZA VIRUS VACCINE

Bivalent Types A & B 5cc size
400cca units/0.5ml

246-2950

1- 11.75 10- 114.50

ORDER NOW—SUPPLIES ARE LIMITED

ISOXSUPRINE HCL

Comparable to Vasodilan

10 mg. Tabs

003-9350	1x100	3.65
003-9355	1x1000	32.40

20 mg. Tabs

003-9360	1x100	6.50
003-9365	1x500	29.70

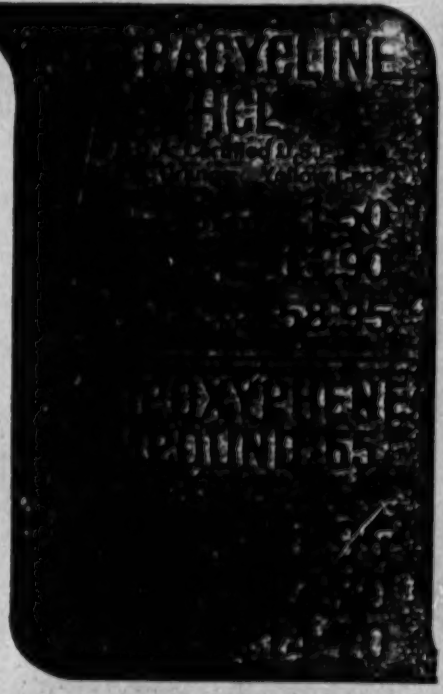
NEW LOW PRICE!

HYDRO-CHLOROTHIAZIDE

Comparable to Hydrodiuril

50 mg. Tabs

003-9190	1x100	1.00
003-9192	1x1000	4.50



VITAMIN B12

1000 mcg/cc (Crystalline)

300-2040 10cc Vials

10 Vials 3.85 50 Vials 17.95

300-2060 30cc Vials

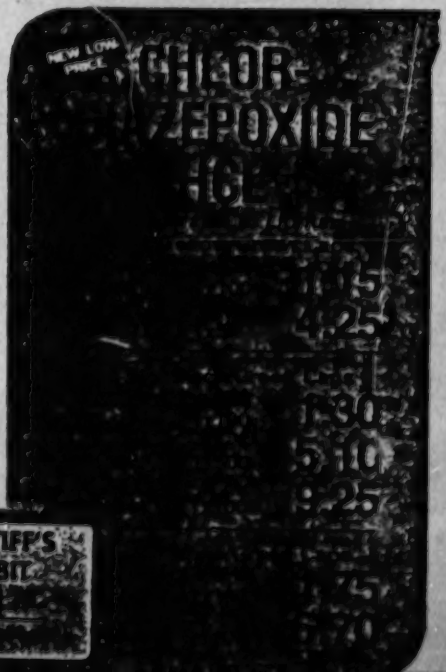
10 Vials 5.50 50 Vials 26.90

AMPICILLIN TRIHYDRATE

F.D.A. Certified

250 mg. Maroon & Grey Caps

310-0010	1x100	4.70
310-0015	1x500	
310-0013	1x1000	



PLAINTIFF'S EXHIBIT 51

Plaintiff's Exhibit 51

GENERIC TABLETS and CAPSULES

IMPORTANT—PLEASE USE PRODUCT NUMBERS WHEN ORDERING

QUINIDINE SULFATE Caps. U.S.P. 5 gr.	004-4332	100	8.40
	004-4333	1M	78.30
RAUWOLFIA SERPENTIA, N.F.			
(Comparable to Raudixin)			
50 mg. S. C. Red Tabs	004-4360	1M	4.15
	004-4361	1x5M	20.45
100 mg. S. C. Red Tabs	004-4400	1M	5.80
	004-4401	1x5M	27.75
RESERPINE U.S.P.			
(Comparable to Serpasil)			
0.1 mg. Tabs	004-4540	1M	1.25
	004-4541	1x5M	5.55
0.25 mg. Tabs	004-4580	1M	1.30
	004-4581	1x5M	5.50

SPASMOL

Comparable to Cyclospasmol

200 mg. Blue Capsules

003-5310 1x100 **1.70** 003-5315 1x1000 **13.75**

R-H-H Pink Tabs	004-7210	100	1.75
(Comparable to Ser-Ap-Es)	004-7212	1M	14.45
Each pink tab contains: Reserpine 0.1 mg., Hydralazine 25 mg., Hydrochlorothiazide 15 mg.			
SACCHARIN U.S.P.			
¼ gr. White Tabs	004-5080	1M	.80
	004-5080	5x1M	3.75
½ gr. White Tabs	004-5100	1M	1.25
	003-5100	5x1M	6.00
SENACTIN Tabs	004-5290	100	.75
(Comparable to Senokot)	004-5295	1M	3.85
Each tab contains: Standardized Extract of Senna Fruit 217 mg.			
SHERDECON Tabs	004-7250	100	1.65
(Comparable to Naldecon)	004-7257	1M	13.60
SHERFACT Tabs	003-0180	100	1.30
(Comparable to Actifed)	003-0185	1M	9.45
Each tab contains: Tripolidine Hcl 2.5 mg., Pseudoephedrine Hcl 60 mg.			

SHERDECON Tabs

Comparable to Naldecon

004-7250 1x100 **1.65**

004-7257 1x1000 **13.60**

SHERRYLAC Tabs	003-4301	1M	3.00
(Comparable to Titralac)	003-4301	5x1M	14.40
Each tab contains: Calcium Carbonate 0.42 gm., Glycine 0.18 gm.			
SHERRYSWEET Tabs	004-5330	1M	1.95
Each tab contains: Saccharin 16.2 mg. and Potassium Bitartrate	004-5330	5x1M	9.25
SIN-A-PAP Tabs	004-1580	100	1.10
(Comparable to Sinutabs)	004-1581	1M	7.45
Each pink tab contains: APAP 150 mg., Phenyltoloxamine 22 mg., Phenacetin 150 mg., Phenylpropanolamine Hcl 25 mg.	004-1581	5x1M	34.95
SINEEZE Caps *(Comparable to Omex)*	003-5740	100	1.65
Each blue & white cap contains: APAP 325 mg., Phenylpropanolamine Hcl 18 mg.	003-5745	1M	12.95

SINO-CLEAR Multilayer Tabs	004-5360	1M	9.70
Prompt Relief of Colds, Hay Fever, Sinus	004-5360	5x1M	44.95
Each tab contains: Caffeine 10 mg., Chlorpheniramine Mal. 2 mg., Phenacetin 100 mg., Phenylephrine Hcl 5 mg., Salicylamide 227 mg.			
SODIUM FLUORIDE			
2.2 mg. White Tabs	004-5480	1M	1.55
	004-5480	5x1M	7.10
2.2 mg. Chewable, Flavored Tabs	004-5490	1M	1.65
	004-5490	5x1M	7.75
SODIUM SALICYLATE U.S.P.			
5 gr. E. C. Red Tabs	004-5600	1M	4.75
	004-5600	5x1M	22.95
10 gr. E. C. Red Tabs	004-5620	1M	6.95
	004-5620	5x1M	32.95
SPASMOL Caps			
(Comparable to Cyclospasmol)			
200 mg. Blue Caps	003-5310	100	1.70
	003-5290	500	13.75
400 mg. Red/Blue Caps	003-5293	100	3.10
	003-5290	500	13.60
SPASMTABS	003-9200	1M	1.95
(Comparable to Donnatal)	003-9201	1x5M	8.75
Each white tab contains: Atropine Sulfate 0.0194 mg., Hyoscine HBr .0065 mg., Hyoscyamine SO. 0.1037 mg., Phenobarbital ¼ gr.			

NEW LOW PRICE

SHERFACT

Comparable to Actifed

White Tablets

003-0180 1x100 **1.30** 003-0185 1x1000 **9.45**

SPASTOLATE Caps	003-9260	1M	8.05
(Comparable to Donnatal)	003-9260	5x1M	38.10
Each green & clear cap contains: Atropine Sulfate 0.0194 mg., Hyoscine HBr .0065 mg., Hyoscyamine SO, 0.1037 mg., Phenobarbital 16.2 mg.			
SPASTOLATE T.D. Caps	003-9280	1M	8.90
(Comparable to Donnatal Extentabs)	003-9280	5x1M	41.25
Each cap contains: Atropine Sulfate 0.0582 mg., Hyoscine HBr 0.0195 mg., Hyoscyamine SO, 0.311 mg., Phenobarbital 50 mg.			
STILBESTROL Tabs U.S.P.			
1.0 mg. White C. T.	004-5840	1M	4.90
	004-5840	5x1M	23.95
1.0 mg. Red E. C.	004-5860	1M	7.95
	004-5860	5x1M	38.95
5 mg. White C. T.	004-5880	1M	7.75
	004-5880	5x1M	37.95
5 mg. Red E. C.	004-5900	1M	10.85
	004-5900	5x1M	52.75
SULFASALAZINE Gold Tabs 500 mg.	004-6170	100	3.25
(Comparable to Azulfidine)	004-6175	500	15.95
SULFISOXAZOLE White Tabs. 0.5 gm.	004-6180	100	2.10
(Comparable to Gantrisin)	004-6181	1M	13.75
TAMINACT T.D. Tabs	004-7260	100	1.75
(Comparable to Triaminic)			
Each tab contains: Pheniramine Mal. 25 mg., Phenylpropanolamine Hcl 50 mg., Pyrilamine Mal. 25 mg.			

SERVICE—ECONOMY—DEPENDABILITY

F = CIII, CIV, CV, DEA Registry # Required

IMPORTANT—PLEASE USE PRODUCT NUMBERS WHEN ORDERING

156-1800	CO-PYRONIL Caps. 100	1	7.85
156-1808	Caps. 1000	1	68.50
	CORDRAN		
156-1902	Cream, 7½ gm., 0.5%	1	1.55
156-1900	Cream, 15 gm., 0.5%	1	2.45
156-1905	Cream, 60 gm., 0.5%	1	6.95
156-2010	½ Strength Cream, 60 gm.	1	3.75
156-2005	0.05% Lotion, 60cc	1	6.95
156-1950	Ointment, 15 gm., 0.5%	1	2.45
156-1955	Ointment, 60 gm., 0.5%	1	6.95
156-2015	½ Strength Oint., 60 gm.	1	3.75
156-2115	Tape, 80" x 3"	1	5.15
	CORDRAN-N		
156-2050	Cream, 15 gm.	1	2.65
156-2055	Cream, 60 gm.	1	7.35
156-2100	Ointment, 15 gm.	1	2.65
156-2105	Ointment, 60 gm.	1	7.35
	CORICIDIN		
214-1700	"D" Tabs. 100	1	3.10
214-1705	"D" Indust. Pack, 400	1	8.70
214-1242	Demilets, 24	6	4.20
214-1200 •	Tabs. 100	1	2.50
214-1220	Tabs. Indust. Pack, 400	1	7.90

DIPHTHERIA PERTUSSIS TETANUS TOXOID

Alum Precipitate, 7.5cc Vial

174-1280 1 Vial **2.15**

174-1260 10 Vials **19.95**

214-1300	CORIFORTE Caps. 100	1	6.35
128-0305	CORT-ACNE Lot., 2 oz.	1	3.35
	COR-TAR-QUIN		
132-1310	¼% Creme, 1 oz.	1	2.60
132-1315	½% Creme, 1 oz.	1	4.55
	CORT-DOME		
132-0500 •	¼% Creme, 1 oz.	1	1.70
132-0605 •	½% Creme, 1 oz.	1	2.90
254-2429	CORTENEMA, 7x60cc	1	11.45
	CORTISPORIN		
122-1700	Ointment, ½ oz.	1	3.00
122-1900	Ophth. Oint., ½ oz.	1	1.50
122-2000	Ophth. Susp., 5cc	1	2.10
122-1810	Otic Drops, 10cc	1	3.00
166-2500	CO-SALT, 8 oz.	1	2.75
	COTAZYM		
184-03	Caps. 100	1	6.35
164-2435	CO-TYLENOL Tabs. 48	1	2.15
	COUMADIN *(Warfarin)*		
138-0100	2 mg. Tabs. 100	1	5.00
138-0300	2½ mg. Tabs. 100	1	5.05
138-0500	5 mg. Tabs. 100	1	5.50
138-0600	5 mg. Tabs. 1000	1	52.75
138-0700	7½ mg. Tabs. 100	1	6.70
138-0900	10 mg. Tabs. 100	1	7.95
342-0800	CREAMALIN Tabs. 200	1	3.55
	CRUEX		
187-3435	Spray Powder, 4 oz.	1	1.60
	CRYSTICILLIN *(Procaine Penicillin G)*		
222-0325	300,000 U.S. 10cc	10	7.90
222-C325	300,000 U.S. 10cc	100	72.50
222-0380	600,000 U.S. 12cc	10	15.20
222-0390	600,000 U.S. 12cc	100	141.25
	CRYSTODIGIN *(Digitoxin)*		
156-2153 •	0.1 mg. Tabs. 100	1	1.15
	CU-7		
212-0775	Copper Intrauterine, 6	1	62.95
212-0775	Copper Intrauterine, 6	5	315.95
230-1200	C.V.P. Caps. 100	1	7.95
230-1205	Caps. 500	1	35.95
	CYCLAINE HCL *(Hexylcaine Hcl)*		
172-1450	5% Topical, 60cc	1	2.90
	CYCLOGYL		
104-2500	0.5% Ophth. Sol., 15cc	1	5.20
104-2600	1% Ophth. Sol., 15cc	1	5.95
	CYCLOSPASMOL *(Cyclandelate)*		
144-0200 •	200 mg. Caps. 100	1	8.00
	CYTOMEL *(Liothyronine)*		
220-2000	5 mcg. Tabs. 100	1	1.90
220-2100 •	25 mcg. Tabs. 100	1	2.70
220-2105 •	25 mcg. Tabs. 1000	1	25.50
220-2115 •	50 mcg. Tabs. 100	1	4.10
	CYTOXAN		
168-0750	50 mg. Tabs. 100	1	23.35

D

219-0400	DACRIOSE Sol. 4 oz.	1	1.90
	DALMANE *(Flurazepam Hcl)*		
220-0710	15 mg. Caps. 100 CIV	1	7.50
200-0715	15 mg. Caps. 500 CIV	1	35.95
200-0730	30 mg. Caps. 100 CIV	1	8.95
200-0735	30 mg. Caps. 500 CIV	1	43.75
	DANOCRINE		
242-0900	200 mg. Caps. 100	1	97.50
	DANTRIUM		
136-0072	25 mg. Caps. 100	1	9.25
136-0082	100 mg. Caps. 100	1	17.85
172-1700	DARANIDE Tabs. 100	1	8.25
	DARICON		
162-0360	10 mg. Tabs. 60	1	5.90
162-0365	10 mg. Tabs. 500	1	52.60
156-2340	DARVOCET-N Tabs. 100 CIV	1	4.50
156-2345	Tabs. 500 CIV	1	20.70
	DARVOCET-N 100		
156-2347	Tabs. 100 CIV	1	8.30
156-2348	Tabs. 500 CIV	1	43.20
	DARVON *(Propoxyphene Hcl)*		
156-2350	32 mg. Caps. 100 CIV	1	3.75
156-2355	32 mg. Caps. 500 CIV	1	17.75
156-2400 •	65 mg. Caps. 100 CIV	1	6.90
156-2405 •	65 mg. Caps. 500 CIV	1	32.50
	DARVON COMPOUND		
156-2450	Caps. 100 CIV	1	4.00
156-2455	Caps. 500 CIV	1	19.20
156-2500 •	'65' Caps. 100 CIV	1	7.25
156-2505 •	'65' Caps. 500 CIV	1	33.75
	DARVON-N CIV *(Propoxyphene Napsylate)*		
156-2310	100 mg. Tabs. 100	1	8.05
	DARVON-w/A.S.A.		
156-2510	Caps. 100 CIV	1	7.20
156-2515	Caps. 500 CIV	1	35.40

DECADRON

4 mg/cc, 5cc Vial

172-1900 1 Vial **5.50**

172-1900 10 Vials **53.30**

	DARVON-N w/A.S.A.		
156-2325	Tabs. 100 CIV	1	8.15
156-2330	Tabs. 500 CIV	1	39.45
	DAXOLIN		
132-1950	10 mg. Caps. 100	1	10.90
132-1960	25 mg. Caps. 100	1	16.50
132-1970	50 mg. Caps. 100	1	21.90
	DBI *(Phenformin Hcl)*		
140-0460	50 mg. T.D. Caps. 100	1	13.25
140-0465	50 mg. T.D. Caps. 1000	1	132.95
140-0490	25 mg. Tabs. 100	1	5.95
198-0220	DEANER-250 Tabs. 50	1	15.40
847-0430	DEBROX Drops, 15cc	1	1.65
	DECA-DURABOLIN *(Nandrolone Decanoate)*		
184-0900	50 mg./cc Vial, 2cc	1	8.45
184-0800	50 mg./cc Vial, 4 x 1cc	1	18.50
184-0910	100 mg./cc Vial, 2cc	1	15.25
	DECADRON *(Dexamethasone)*		
172-2100 •	Elixir, 100cc	1	3.45
172-1900 •	4 mg./cc Injection, 5cc	1	5.50
172-1900 •	4 mg./cc Injection, 5cc	10	53.30
172-1903 •	4 mg./cc Injection, 25cc	1	26.65
172-2150	0.1% Ophth. Sol., 2.5cc	1	1.65
172-2155	0.1% Ophth. Sol., 5cc	1	2.90
172-1930	0.5 mg. Tabs. 100	1	11.20
172-2000 •	0.75 mg. Tabs. 100	1	13.70
172-2250	0.1% Top. Cream, 15 gm.	1	2.20
172-2200	Turbinaire 12.6 gm.	1	5.70

COMBISTIX Strips

106-0900 1 x 100 **9.75**

106-0900 10 x 100 **96.95**

	DECADRON w/XYLOCAINE		
172-2300	Injection, 5cc	1	5.60
172-2300	Injection, 5cc	10	55.00
172-2400	DECAGESIC Tabs. 100	1	7.10
	DECLOMYCIN		
154-4500	150 mg. Caps. 16	1	5.05
154-4505	150 mg. Caps. 100	1	30.50
154-4805	Syrup, 16 oz.	1	18.95
	DECLOSTATIN		
154-5000	Caps. 16	1	5.85
154-5005	Caps. 100	1	35.15
	DECONAMINE		
219-0440	Caps. 100	1	10.90
	DELADUMONE		
222-0400 •	Vial, 5cc	1	4.40
222-0400 •	Vial, 5cc	5	20.50
	DELADUMONE OB		
222-0425 •	Vial, 2cc	1	5.10
222-0425 •	Vial, 2cc	10	48.50
	DELALUTIN *(Hydroxyprogesterone Caproate)*		
222-0500 •	125 mg./cc Vial, 10cc	1	8.40
222-0500 •	125 mg./cc Vial, 10cc	5	40.75
222-0600 •	250 mg./cc Vial, 5cc	1	7.55
222-0600 •	250 mg./cc Vial, 5cc	5	36.65
	DELATESTRYL *(Testosterone Enathanate)*		
222-0700 •	200 mg./cc Vial, 5cc	1	7.25
	DELESTROGEN *(Estradiol Valerate)*		
222-0800 •	10 mg./cc Vial, 5cc	1	3.95
222-0800 •	10 mg./cc Vial, 5cc	5	19.00
222-0900 •	20 mg./cc Vial, 5cc	1	5.65
222-0900 •	20 mg./cc Vial, 5cc	5	27.15
222-1000 •	40 mg./cc Vial, 5cc	1	9.85
222-1000 •	40 mg./cc Vial, 5cc	5	47.20

• Generics Available on Pages 4-32

For CIII, CIV, CV, DEA Registry # Required

PLAINTIFF'S EXHIBIT 52

Darby Drug Co., Inc.

There can only be ONE No. 1

AMPICILLIN TRIHYDRATE

F.D.A. Certified

250 mg. Caps.	500 mg. Caps
310-0010	310-0016
100 — 4.70	100 — 9.30
310-0015	310-0018
500 — 22.85	500 — 45.50
310-0013	310-0018
1M — 45.20	2x500 — 90.50

TETRACYCLINE HCL

F.D.A. Certified U.S.P.

250 mg. Caps Orange/Yellow

310-1825 1M — 12.25

310-1825 5M — 60.50

500 mg. Caps Black/Yellow

310-1870 100 — 2.70

310-1875 1M — 23.25

PREDNISOLONE TABS

5 mg.

004-3242 1M — 8.65

004-3243 5M — 41.95

PROPOXYPHENE @ COMPOUND-65

(Similar to Darvon Compound-65)

004-3830 100 — 1.95

004-3832 500 — 8.00

004-3834 1M — 15.35

HYDROCHLORO-THIAZIDE

(Similar to Hydrodiuril)

50 mg. Tabs

003-9190 100 — 1.00

003-9192 1M — 5.65

PAVAGEN T.D. CAPS

(Papaverine HCL S.F.)

150 mg.

004-1248 100 — 1.95

004-1249 500 — 7.95

004-1247 1M — 14.95

STERILE DISPOSABLE SYRINGES

MANUFACTURED IN U.S.A. • 3cc W/NEEDLE

321-1040 25 x ⅝	321-1030 22 x 1¼	321-1010 21 x 1
321-1035 23 x 1	321-1025 22 x 1½	321-1005 20 x 1½
321-1020 22 x 1	321-1015 21 x 1½	321-1000 20 x 1

100 6.40

1000 61.95

CHLORDIAZEPOXIDE HCL (Similar to Librium)

5 mg. Caps Yellow/Green	10 mg. Caps Black/Green	25 mg. Caps White/Green
003-4870 100 — 1.20	003-4880 100 — 1.40	003-4890 100 — 1.95
003-4872 500 — 4.35	003-4882 500 — 5.55	003-4892 500 — 8.50
003-4872 2x500 — 8.40	003-4885 1M — 10.30	003-4892 2x500 — 15.95

PLAINTIFF'S EXHIBIT 52

Plaintiff's Exhibit 52

Tablets/Capsules

IMPORTANT: Please add STOCK No. when ordering.

		1M	5x1M
Cold Tabs #2 with DMH (Rose)		15.50	75.25
003-5310	Phenylpropanolamine Hcl. 25 mg. — Terpin Hydrate 3½ gr. — Chlorpheniramine Maleate 2 mg. — Acetaminophen 5 gr. — Pyrilamine Maleate 12 mg. — Dextromethorphan HBr 7½ mg.		
Cold Capsules—Mild (Yellow/Blue)		8.75	42.50
003-5040	Acetylsalicylic Acid 3½ gr. — Pyrilamine Mal. 12 mg. — Phenacetin 3½ gr. — Caffeine ½ gr.		
Cold Capsules—Medium (Yellow/Purple)		11.50	56.50
003-5080	Aspirin 3½ gr. — Caffeine ½ gr. — Phenacetin 3½ gr. — Pyrilamine Mal. 25 mg.		
Cold Capsules—Forte (Brown/White)		10.90	53.20
003-5080	Aspirin 3½ gr. — Camphor ¼ gr. — Phenacetin 1½ gr. — Podophyllum 1/60 gr. — Quinine Sulfate ½ gr. — Aloin 1/10 gr. — Atropine Sulfate 1/1000 gr.		
Conjugated Estrogens U.S.P.			
003-5181	0.625 mg. Tabs (Maroon) 003-5180 (100—2.15)	17.50	
003-5221	1.25 mg. Tabs (Yellow) 003-5220 (100—3.30)	27.95	
003-5288	2.50 mg. Tabs (Purple) 003-5280 (100—5.65)	52.75	
Cortisone Tablets			
003-5300	25 mg. (White) (100—3.75)	34.90	
Cough Wafers/Menthciated		2.75	12.95
003-5340	Benzocaine ½ gr. — Licorice P.E. 1/16 gr. — Oil of Anise, Eucalyptol and Menthol		
CYCLANDELATE (Similar to Cyclospasmol)			
003-5316	200 mg. Caps (Blue) 003-5310 (100—1.75)	13.95	
003-5230	400 mg. Caps (100—3.45) 003-5293 (500—14.95)		
CYTOMINE® Tabs (Similar to Cytomel)			
003-5336	25 mcg. (White) 003-5330 (100—1.10)	7.45	
003-5357	50 mcg. (White) 003-5355 (100—1.15)	8.95	

ONE OF AMERICA'S MOST POPULAR GENERIC FORMULAS

		1M	5x1M
DARLITE® (Capsule Shaped Tabs) (S.C. Brown)		7.25	34.95
003-5841	D 400 I.U. — A 5,000 I.U. — C 60 mg. — B1 3.5 mg. — B2 2.4 mg. — B6 0.6 mg. — B12 1.5 mcg. — E 3 I.U. — Cal. Pan. 3.5 mg. — Niacinamide 25 mg. — Pot. Sulfate 5 mg. — Zinc Sulfate 3.2 mg. — Dried Yeast 10 mg. — Wheat Germ Oil 10 mg. — Biotin 3 mcg. — Choline Bitar. 5 mg. — Dical. Phos. 110 mg. — Inositol 5 mg. — Phosphorous 65 mg. — Ferrous Sulf. 12 mg. — Iodine (Pot. Iodide) 0.12 mg. — Copper Sulfate 0.05 mg. — Manganese Sulf. 0.05 mg. — Magnesium Sulf. 5 mg. — Para-Amino-Benzoic Acid 5 mg.		
	Also Available 003-5840 100—.90 10x100—3.55		
		1M	5x1M
DECONGEST Tabs (White) (Similar to Dristan) (100—.95)		8.75	
003-5710	Phenylephrine Hcl. 5 mg. — Phenindamine Tartrate 10 mg. — Aspirin, Caffeine — Alum. Hydroxide — Magnesium Carb. Co-dried gel.		
DECONGESTIVE T.D. Caps 003-5720 (250—5.65)		21.50	
003-5721	Chlorpheniramine Maleate 8 mg. — Phenylephrine Hcl. 20 mg. — Methscopolamine Nitrate 2.5 mg.		
DEGENEX Caps (Similar to Ornex) 003-5740 (100—1.65)		12.95	
003-5748	Acetaminophen 325 mg. — Phenylpropanolamine Hcl. 12 mg.		
Dehydrocholic Acid Tabs			
003-5780	3¼ gr. (White)	27.85	
003-5788	3¼ gr. w/Belladonna Alk. (White)	28.90	
DEXAMETHASONE			
003-5820	0.75 mg. Tabs (Green) (100—3.80)	36.30	
003-5840	1.5 mg. Tabs (Pink) (100—4.15)		

Plaintiff's Exhibit 52

C-D

GENERIC GUIDE Section

DARBY

NAME BRAND

CYCLOSPASMOL
200 MG. CAPS
Ives
144-0220 100— 8.40

CYTOMEL
(Sod. Liothyronine)
S.K.F.
25 MCG. TABS
220-0105 100— 2.70
220-0105 1M—25.50
50 MCG. TABS
220-0115 100— 4.10

DARVON CIV
65 MG. PULVULES
(Propoxyphene Hcl.)
Lilly
100— 6.95
500—33.80

DARVON
COMP-65 CIV
Lilly

Propoxyphene Hcl.	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg.

100— 7.25
500—34.20

DECADRON
0.75 MG. TABS
(Dexamethasone)
Merck
100—13.70

DECHOLIN TABS
(Dehydrocholic Acid 3¾ GR.)
Dome
100— 6.55
500—31.70

DELTASONE
5 MG. TABS
(Prednisone)
Upjohn
100—2.30

BRANDED GENERICS by DARBY

ORDER BY NUMBER PLEASE

CYCLANDELATE
200 MG. CAPS
Darby
100— 1.75
1M—13.95

CYTOMINE™
(Sod. Liothyronine)
Darby
25 MCG. TABS
100—1.10
1M—7.45
50 MCG. TABS
100—1.15
1M—8.95

PROPOXYPHENE Hcl. CIV
65 MG. CAPSULES
Darby
100—1.85
500—8.70

PROPOXYPHENE
COMP-65 CIV
Darby

Propoxyphene Hcl.	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg.

100— 1.95
500— 8.00
1M—15.35

DEXAMETHASONE
0.75 MG. TABS
Darby
100— 3.80
10x100—36.30

DEHYDROCHOLIC
ACID
3¾ GR. TABS
Darby
1M—27.85

PREDNISONE
5 MG. TABS
Darby
1M—7.90

IMPORTANT! Please add Stock No. when ordering

C (Continued)

Plaintiff's Exhibit 52

C (Continued)

		Size	Price
	CORICIDIN		
214-1200	tabs. (1M—23.50)	100—	2.40
214-1220	Industrial Pack tabs	400—	8.40
214-1240	Demilets Pediatric	36—	.80
214-1300	Forte caps	100—	6.35
214-1400	Medilets Pediatric	36—	.70
214-1600	Nasal Mist	20cc—	.95
214-1700	"D" Decongestant tabs	100—	2.95
139-0300	Cort-Acne lotion	1oz—	2.20
139-0336	Cort-Acne lotion	2oz—	3.30
	COR-TAR-QUIN CREME		
139-1600	¼%—Tube	4oz—	5.75
139-1316	½%—Tube	1oz—	4.55
139-1300	½%—½ oz. Tube	1—	2.65

COUMADIN
5 mg. tabs.
135-0500 100—5.60 138-0532 1M—53.20

	CORT-DOME CREME		
132-0600	¼%—Tube	1oz—	1.70
132-0650	¼%—Tube	4oz—	4.30
132-0800	½%—½ oz. Tube	1—	1.70
132-0806	½%—Tube	1oz—	2.90
132-0808	1%—Tube	1oz—	5.20
	CORT-DOME LOTION		
138-1110	¼%	4oz—	4.50
164-2429	Cortenema 60cc (Box 7)	1—	11.45
	Cortisporin		
19-1700	Oint. ½ oz.	1—	3.00
19-1616	Otic	10cc—	3.00
19-1800	Ophth. Oint. 1/8 oz.	1—	1.50
19-3000	Ophth. Susp.	5cc—	2.10
173-1310	Cortone 25 mg. tabs	100—	12.30
173-1320	Cortone 25 mg./cc. (10—50.60)	20cc—	5.20
39-1800	Cort-Quin Creme ½%—½ oz.	1—	2.20
87-0400	Cortril Oint. ½oz.	1—	1.50
87-0480	Coryban-D caps	24—	1.00
19-3600	Co-Salt	8oz—	2.65
19-3720	Cosanyl-DM Cough Syrup	1pt.—	4.85
94-0200	Cotazym caps	100—	6.35
94-0410	Cotazym-S	60—	5.25
19-4000	Cotton Swabs J&J	175—	1.20
19-4436	Co-Tylenol tabs	48—	2.15
	COUMADIN (Warfarin Sod.)		
84-0700	2mg.	100—	5.05
84-0800	2.5 mg.	100—	5.05
84-0900	5 mg. (1M—53.20)	100—	5.60
84-0910	7.5 mg	100—	6.80
84-0920	10 mg. (1M—76.95)	100—	8.10
19-4600	Cremelin tabs	200—	3.55
19-4800	Crest Toothpaste Family Size	1—	1.20
19-4400	Crest Toothpaste Mint Flav	1—	1.20
19-4600	Cruex Spray Powder	4oz—	1.60
19-4640	Cruex Spray Powder	12oz—	3.35
	CRYSTICILLIN		
19-4800	300 A.S. 10cc. (50—37.20)	10—	7.90
19-4900	600 A.S. 12cc. (50—72.60)	10—	15.20
	CRYSTODIGIN		
19-5100	0.05 mg	500—	2.55
19-5200	0.1 mg. (5M—32.50)	500—	4.15
19-5300	0.15 mg.	500—	5.45
19-5400	Cuprex	3oz—	2.10
19-5500	Cuprimine 250 mg. caps	50—	10.20
19-5600	Cutlcura Soap Bath Bars	3—	1.65
19-5700	Cyclogesterin Oil	5cc—	5.75

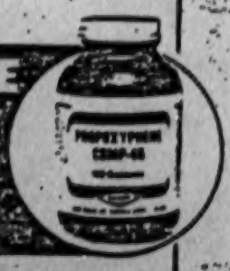
DEA NO. REQUIRED

		Size	Price
104-2600	Cyclogyl 0.5%	15ml—	5.20
104-2600	Cyclogyl 1.0%	15ml—	5.95
	CYCLOSPASMOL (Cyclandelate)		
144-0100	100 mg. tabs. (500—19.50)	100—	4.20
144-0200	200 mg. caps. (500—39.90)	100—	8.40
196-2300	Cytellin	1pt.—	6.10
220-2000	Cytomel 5 mcg.	100—	1.80
220-2100	Cytomel 25 mcg. (1M—25.50)	100—	2.70
220-2116	Cytomel 50 mcg.	100—	4.10
198-0735	Cytoxan 25 mg tabs	100—	11.75
198-0750	Cytoxan 50 mg. tabs	100—	21.80

D

140-0480	D.S.I. 25 mg. tabs. (1M—58.75)	100—	5.95
140-0490	DSI T.D.C. 50 mg. (1M—132.95)	100—	13.50
209-1600	D.H.E. 45 1cc amps	20—	16.70
219-0400	Dacriose Sol	4oz—	1.90
174-1170	Dactil w/Pheno tabs	50—	3.65
188-1001	Dainite-KI tabs. (500—49.70)	100—	10.80
202-0715	Dalmane 15 mg. caps. CIV	100—	7.50
202-0715		500—	35.95
202-0730	Dalmane 30 mg. caps. CIV	100—	8.95
202-0738		500—	43.75
848-0803	Danocrine 200 mg caps	100—	97.50
126-0072	Dantrium 25 mg. caps	100—	10.80
126-0082	Dantrium 100 mg. caps	100—	18.50
188-1016	Dara Shampoo	1pt.—	2.80
173-1700	Daranide 50 mg. tabs	100—	8.25
182-2100	Daraprim tabs.	100—	1.45
220-2300	Darbid 5 mg. tabs (isopropamide)	50—	3.90
168-0080	Daricon 10 mg. tabs. (500—82.60)	60—	6.45
168-0070	Daricon-PB tabs	100—	9.30
165-2340	Darvocet-N tabs. CIV	100—	4.70
165-2346		500—	22.75
165-2347	Darvocet-N 100 tabs. CIV	100—	8.85
165-2348		500—	43.20
165-2360	Darvon 32 mg. CIV	100—	3.80
165-2355		500—	17.95
165-2460	Darvon Comp-32 CIV	100—	4.00
165-2455		500—	19.20
165-2400	Darvon 65 mg. CIV	100—	6.95
165-2405		500—	33.80
165-2500	Darvon Comp-65 CIV	100—	7.25
165-2505		500—	34.20
165-2510	Darvon ASA caps. CIV	100—	7.20
165-2515		500—	35.40
165-2310	Darvon-N tabs. CIV	100—	8.05
165-2315		500—	39.70
165-2320	Darvon-N Susp. 50 mg/5cc. CIV	1pt—	5.40
165-2325	Darvon-N w/A.S.A. CIV	100—	8.15
165-2330		500—	39.45
113-2600	Datril tabs	100—	1.60
113-2610	Datril 500X-Strength caps	72—	1.45

PROPOXYPHENE COMPOUND-65®
(Similar to Darvon Comp-65)
Red & Grey Caps
100—1.95 500—8.00



630a

PLAINTIFF'S EXHIBIT 53

DARBY

DARBY

DRUG CO., INC.

NOW AVAILABLE

INFLUENZA VIRUS VACCINE

Bivalent Types A and B
5cc Size 400CCA units/0.5cc
246-2950

1 — 11.75

10 — 114.50

NEW REDUCED PRICES

HYDRO CHLOROTHIAZIDE

TETRACYCLINE HCL

AMPICILLIN TRIHYDRATE

NEW LOW PRICE!

VITAMIN B-12

20 20.00

70 27.50

CHLORDIAZEPOXIDE

100 1.40

500 5.25

9.70

STERILE DISPOSABLE SYRINGES

3cc W/NEEDLE

100 **6.40**

1000 **61.95**

MANUFACTURED IN U.S.A.

What need

PLAINTIFF'S EXHIBIT 53

DARBY FULL LINE OF PHARMACEUTICALS WILL FILL THEM.

Plaintiff's Exhibit 53

Tablets/Capsules

IMPORTANT! Please add Stock No. when ordering

				1M	5x1M
Cold Tabs #2 with DMH (Rose)			003-5010	15.50	75.25
Phenylpropanolamine Hcl. 25 mg.	Terpin Hydrate 2½ gr.				
Chlorpheniramine Maleate 2 mg.	Acetaminophen 5 gr.				
Pyrilamine Maleate 10 mg.	Dextromethorphan H Br 7½ mg.				
Cold Capsules—Mild (Yellow/Blue)			003-5040	8.75	42.50
Aspirin 3½ gr.	Pyrilamine Mal. 10 mg.				
Phenacetin 2½ gr.	Caffeine ½ gr.				
Cold Capsules—Medium (Yellow/Purple)			003-5060	11.50	56.50
Aspirin 2½ gr.	Caffeine ½ gr.				
Phenacetin 2½ gr.	Pyrilamine Mal. 25 mg.				
Cold Capsules—Forte (Brown/White)			003-5080	10.90	53.20
Aspirin 2½ gr.	Camphor ½ gr.				
Phenacetin 1½ gr.	Podophyllum 1/60 gr.				
Quinine Sulfate ¼ gr.	Alein 1/10 gr.				
Atropine Sulfate 1/1000 gr.					
Conjugated Estrogens U.S.P.					
0.625 mg. Tabs (Maroon)	003-5180	100—2.15	003-5181	17.50	
1.25 mg. Tabs (Yellow)	003-5220	100—3.25	003-5221	29.35	
2.50 mg. Tabs (Purple)	003-5250	100—5.65	003-5285	52.70	
Cortisone Tablets					
25 mg. (White)	003-5300	100—3.75	003-5300	34.90	
Cough Wafers					
Mentholated			003-5340	2.75	12.95
Benzocaine ½ gr. — Licorice P.E. 1/18 gr. Oil of Anise, Eucalyptol and Menthol					
CYCLANDELATE (Similar to Cyclospasmol)					
200 mg. Caps (Blue)	003-5310	100—1.75	003-5315	13.95	
400 mg. Caps 003-5290 100—3.45	003-5293	500—14.95			
CYTOMINE® Tabs (Similar to Cytomel)					
25 mcg. (White)	003-5330	100—1.10	003-5335	7.45	
50 mcg. (White)	003-5355	100—1.15	003-5357	8.95	

ONE OF AMERICA'S MOST POPULAR GENERIC FORMULAS

				1M	5x1M
DARLITE®					
Capsule Shaped Tabs (S.C. Brown)			003-5541	7.25	34.95
D 400 I.u.	Niacinamide 12 mg	Inositol 5 mg.			
A 5,500 I.u.	Pot. Sulfate 6 mg.	Phosphorous 85 mg.			
C 60 mg.	Zinc Sulfate 0.2 mg.	Ferrous Sulf. 12 mg.			
B1 3.5 mg.	Dried Yeast 10 mg.	Iodine (Pot. Iodide) 0.12 mg.			
B2 2.4 mg.	Wheat Germ Oil 10 mg.	Copper Sulfate 0.05 mg.			
B6 0.6 mg.	Biotin 3 mcg.	Manganese Sulf. 0.05 mg.			
B12 1.5 mcg.	Choline Bitar. 5 mg.	Magnesium Sulf. 5 mg.			
E 3 I.u.	Dical. Phosp. 110 mg.	Para-Amino—Benzoic Acid 5 mg.			
Cal. Pan. 3.5 mg.					
Also Available	003-5546	100—.90	10x100—8.55		
DECONGEST (Similar to Dristan)				1M	5x1M
Tabs (White)	003-5710	100— .95	003-5710	8.75	
Phenylephrine Hcl. 5 mg. — Phenindamine Tartrate 10 mg. — Aspirin, Caffeine — Alum. Hydroxide — Magnesium Carb. Co-dried gel.					
DECONGESTIVE					
T.D. Caps	003-5720	250—5.65	003-5721	21.50	
Chlorpheniramine Maleate 8 mg.	Phenylephrine Hcl. 20 mg.				
Methoscopolamine Nitrate 2.5 mg.					
DEGENEX (Similar to Ornex)					
Caps	003-5745	100—1.65	003-5745	12.95	
Acetaminophen 325 mg.	Phenylpropanolamine Hcl. 18 mg.				
Dehydrocholic Acid					
Tabs 3¾ gr. (White)			003-5760	27.85	
Tabs 3¾ gr. w/Belladona Alk. (White)			003-5780	28.90	
DEXAMETHASONE					
0.75 mg. Tabs (Green)	003-5830	100—3.80	003-5830	36.30	
1.5 mg. Tabs (Pink)	003-5840	100—4.15			

C-D

GENERIC GUIDE Section

DARBY

NAME BRAND

CYCLOSPASMOL
200 MG. CAPS
Ives
144-0300 100— 8.40

CYTOMEL
(Sod. Liothyronine) U.S.P.
25 MCG. TABS
220-0100 100— 2.70
220-0106 1M—25.50
50 MCG. TABS
220-0110 100— 4.10

DARVON CIV
65 MG. PULVULES
(Propoxyphene Hcl.)
Lilly
188-0400 100— 6.95
188-0402 500—33.80

DARVON
COMP-65 CIV
Lilly

Propoxyphene Hcl.	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg.

188-0500 100— 7.25
188-0506 500—34.20

DECADRON
0.75 MG. TABS
(Dexamethasone)
Merck
172-0009 100—13.70

DECHOLIN TABS
(Dehydrocholic Acid 3¾ GR.)
Dome
133-0000 100— 6.55
133-0006 500—31.70

DELTASONE
5 MG. TABS
(Prednisone)
Upjohn
229-0100 100—2.30

"BRANDED GENERICS" by DARBY

ORDER BY NUMBER PLEASE

CYCLANDELATE
200 MG. CAPS
Darby
003-8310 100— 1.75
003-8318 1M—13.95

CYTOMINE™
(Sod. Liothyronine)
Darby
25 MCG. TABS
003-8330 100—1.10
003-8338 1M—7.45
50 MCG. TABS
003-8350 100—1.15
003-8357 1M—8.95

PROPOXYPHENE Hcl. CIV
65 MG. CAPSULES
Darby
004-3820 100—1.85
004-3822 500—8.70

PROPOXYPHENE
COMP-65 CIV
Darby

Propoxyphene Hcl.	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg

004-3850 100— 1.95
004-3822 500— 7.70
004-3834 1M—14.70

DEXAMETHASONE
0.75 MG. TABS
Darby
003-8330 100— 3.80
003-8336 10x100—36.30

DEHYDROCHOLIC
ACID
3¾ GR. TABS
Darby
005-8760 1M—27.85

PREDNISONE
5 MG. TABS
Darby
004-8342 1M—7.40

Plaintiff's Exhibit 53

C (Continued)

		Size	Price
	Cordran Tape (Large)	1—	6.15
	Corega Dent. Adhes. Pdr. 3.5 oz.	1—	1.70
	CORICIDIN		
	tabs.	100—	2.55
	Industrial Pack tabs	400—	8.40
	Demilets Pediatric	36—	.85
	Forte caps	100—	6.35
	Medilets Pediatric	36—	.70
	Nasal Mist	20cc—	1.00
	"D" Decongestant tabs	100—	3.10
	Cort-Acne lotion	1oz—	2.30
	Cort-Acne lotion	2oz—	3.40

	COR-TAR-QUIN CREME		
	¼%—Tube	4oz—	5.75
	½%—Tube	1oz—	4.55
	1%—½ oz. Tube	1—	2.65
	CORT-DOME CREME		
	¼%—Tube	1oz—	1.70
	½%—Tube	4oz—	4.30
	1%—½ oz. Tube	1—	1.70
	2½%—Tube	1oz—	2.90
	1%—Tube	1oz—	5.20
	CORT-DOME LOTION		
	¼%	4oz—	4.50
	Corteneme 60cc (Box 7)	1—	11.45
	Cortisporin		
	Oint. ⅛ oz.	1—	3.00
	Otic	10cc—	3.00
	Opntn. Oint. 1/8 oz	1—	1.50
	Opnth. Susp.	5cc—	2.10
	Cortone 25 mg. tabs	100—	12.30
	Cortone 25 mg./cc. (10—50.60)	20cc—	5.20
	Cortril Oint. ½oz.	1—	1.50
	Coryban-D caps	24—	1.00
	Co-Salt	8oz—	2.65
	Cotazym caps	100—	6.35
	Cotazym-S	60—	5.25
	Cotton Swabs J&J	175—	1.20
	Co-Tylenol tabs	48—	2.15
	COUMADIN (Warfarin Sod.)		
	2mg	100—	5.05
	2.5 mg	100—	5.05
	5 mg. (1M—53.20)	100—	5.60
	7.5 mg	100—	6.80
	10 mg. (1M—76.95)	100—	8.10
	Creamalin tabs.	200—	3.55
	Crest Toothpaste Family Size	1—	1.25
	Crest Toothpaste Mint Flav	1—	1.25
	Cruex Spray Powder	4oz—	1.60
	Cruex Spray Powder	12oz—	3.35
	CRYSTICILLIN		
	300 A.S. 10cc. (50—37.20)	10—	7.90
	300 A.S. 12cc. (50—72.60)	10—	15.20
	CRYSTODIGIN		
	0.05 mg.	500—	2.55
	0.1 mg. (5M—32.50)	500—	4.15
	0.2 5 mg.	500—	5.45
	Cuprex	3oz—	2.10
	Cuprimine 250 mg. caps	50—	10.20
	Cuticura Soap Bath Bars	3—	1.65
	Cyclogesterin Oil	5cc—	5.75

DEA NO. REQUIRED

C (Continued)

		Size	Price
104-2500	Cyclogyl 0.5%	15ml—	5.50
104-2600	Cyclogyl 1.0%	15ml—	6.25
	CYCLOSPASMOL (Cyclandelate)		
144-0100	100 mg. tabs. (500—19.50)	100—	4.20
144-0200	200 mg. caps. (500—39.90)	100—	8.40
188-2300	Cytellin	1pt.—	6.10
220-2000	Cytomel 5 mcg.	100—	1.80
220-2100	Cytomel 25 mcg. (1M—25.50)	100—	2.70
220-2115	Cytomel 50 mcg.	100—	4.10
168-0725	Cytoxan 25 mg tabs	100—	12.70
168-0750	Cytoxan 50 mg. tabs	100—	23.35

D

140-0460	D.B.I. 25 mg. tabs. (1M—56.75)	100—	5.95
140-0480	DBI T.D.C. 50 mg. (1M—132.95)	100—	13.50
208-1500	D.H.E. 45 1cc amps	20—	16.80
118-0400	Dacriose Sol	4oz—	2.00
174-1170	Dactil w/Pheno tabs	50—	3.65
180-1001	Dainite-KI tabs. (500—49.70)	100—	10.80
200-0710	Daimane 15 mg. caps. CIV	100—	7.50
200-0715		500—	35.95
200-0730	Daimane 30 mg. caps. CIV	100—	8.95
200-0735		500—	43.75
240-0900	Danocrine 200 mg caps	100—	97.50
126-0072	Dantrium 25 mg. caps	100—	10.60
126-0082	Dantrium 100 mg. caps	100—	18.50
185-1010	Dara Shampoo	1pt.—	2.90
172-1700	Daranide 50 mg. tabs	100—	8.25
122-2100	Daraprim tabs.	100—	1.45
220-2300	Darbid 5 mg. tabs (isopropamide)	50—	3.90
162-0360	Daricon 10 mg. tabs. (500—52.60)	60—	6.45
162-0370	Daricon-PB tabs	100—	9.30
188-2340	Darvocet-N tabs. CIV	100—	4.70
188-2345		500—	22.75
188-2347	Darvocet-N 100 tabs. CIV	100—	8.85
188-2348		500—	43.20
188-2360	Darvon 32 mg. CIV	100—	3.80
188-2365		500—	17.95
188-2480	Darvon Comp-32. CIV	100—	4.00
188-2485		500—	19.20
188-2400	Darvon 65 mg. CIV	100—	6.95
188-2405		500—	33.80
188-2800	Darvon Comp-65. CIV	100—	7.25
188-2805		500—	34.20
188-2810	Darvon ASA caps. CIV	100—	7.20
188-2815		500—	35.40
188-2310	Darvon-N tabs. CIV	100—	8.05
188-2315		500—	39.70
188-2320	Darvon-N w/A.S.A. CIV	100—	8.15
188-2330		500—	39.45
113-2600	Datril tabs	100—	1.60
113-2610	Datril 500X-Strength caps	72—	1.50

PLAINTIFF'S EXHIBIT 54

Darby Drug Co. Inc.

Pharmacy Edition

Summer '76

CHLORDIAZEPOXIDE HCL.

(Similar to Librium)

NOW AVAILABLE

PATENT EXPIRED

5 mg. Caps (Yellow & Green)	10 mg. Caps (Black & Green)	25 mg. Caps (White & Green)
003-4870 100 – 2.00	003-4880 100 – 2.45	003-4890 100 – 3.05
003-4872 500 – 9.25	003-4882 500 – 11.50	003-4892 500 – 17.00
2x 003-4872 500 – 17.95	003-4885 1M – 22.25	2x 003-4892 500 – 33.00

TETRACYCLINE HCL U.S.P.

F.D.A. Certified

250 mg. Caps (Orange & Yellow)	500 mg. Caps (Black & Yellow)
310-1825 1M – 11.65	310-1870 100 – 2.50
5 x 1M – 56.95	310-1875 1M – 21.95

AMPICILLIN TRIHYDRATE

F.D.A. Certified

250 mg. Caps	500 mg. Caps
310-0010 100 – 4.70	310-0016 100 – 9.20
310-0015 500 – 22.85	310-0018 500 – 44.85
310-0013 1M – 43.50	310-0018 2 x 500 – 89.00

PROPOXYPHENE COMPOUND-65

(Similar to Darvon Compound-65)

004-3830 100 – 1.80
004-3832 500 – 8.95
004-3834 1M – 13.60

HYDROCHLORO-THIAZIDE

(Similar to Hydrodiuril)

50 mg. Tabs
003-9190 100 – .75
003-9192 1M – 4.55

SULFISOXAZOLE

(Similar to Gantrisin)

0.5 gm Tabs

004-6181
1M – 12.90
5 x 1M – 62.40

ALLERFRIN Tabs

(Similar to Actifed)

003-0180 100 – 1.60
003-0185 1M – 12.95

PAVAGEN

(Papaverine HCL N.F.)
Timed Release Capsules

Papaverine HCL 150 mg.

004-1248 100 – 1.95
004-1249 500 – 7.95
004-1247 1M – 14.95

TRI-HYDROSERPINE TABS

(Similar to SER-AP-ES)

004-7210 100 – 1.45
004-7212 1M – 9.75

100 Banks Ave., Rockville Centre, N.Y. 11570

PLAINTIFF'S EXHIBIT

Plaintiff's Exhibit 54

Tablets/Capsules

IMPORTANT
Please add STOCK No. when ordering.

		1M	5x1M
Cold Capsules—Mild (Yellow/Blue)		8.75	42.50
003-5040	Acetylsalicylic Acid [illegible] gr. Acetophenetidin [illegible] gr. Pyrilamine Mal. [illegible] mg. Caffeine [illegible] gr.		
Cold Capsules—Medium (Yellow/Purple)		11.50	56.50
003-5060	Salicylamide [illegible] gr. Acetophenetidin [illegible] gr. Caffeine [illegible] gr. Pyrilamine Mal. [illegible] mg.		
Cold Capsules—Forte (Brown/White)		10.90	53.20
003-5080	Acetylsalicylic Acid [illegible] gr. Acetophenetidin [illegible] gr. Quinine Sulfate [illegible] gr. Atropine Sulfate 1/1000 gr. Camphor [illegible] gr. Pecopyrilin [illegible] gr. Alpin [illegible] gr.		
Conjugated Estrogens U.S.P.			
003-5181	0.625 mg. Tabs (Maroon) 003-5180 (100—1.35)	15.70	
003-5221	1.25 mg. Tabs (Yellow) 003-5220 (100—3.15)	24.50	
003-5280	2.50 mg. Tabs (Purple) (100—5.40)	51.90	
Cortisone Tablets			
003-5300	25 mg. (White) (100—3.75)	34.90	
Cough Wafers/Mentholated		2.75	12.95
003-5340	Benzocaine [illegible] gr. — Licorice P.E. 1/16 gr. Oil of Anise, Eucalyptol and Menthol		
CYCLANDELATE (Similar to Cyclospasmol)			
003-5315	200 mg. Caps (Blue) 003-5313 (100—2.45)	20.70	
003-5290	400 mg. Caps (100—3.25)		
CYTOMINE® Tabs (Similar to Cytomel)			
003-5335	25 mcg. (White) 003-5330 (100—1.10)	7.45	
003-5357	50 mcg. (White) 003-5355 (100—1.15)	8.95	

ONE OF AMERICA'S MOST POPULAR GENERIC FORMULAS

		1M	5x1M
DARLITE® (Capsule Shaped Tabs) (S.C. Brown)		6.50	31.00

003-5541

D	400 un.	Niacinamide	12 mg.	Inositol	[illegible] mg.
A	8,800 un.	Pot. Sulfate	6 mg.	Phosphorous	[illegible] mg.
C	60 mg.	Zinc Sulfate	3.2 mg.	Ferrous Sulf.	12 mg.
B1	3.5 mg.	Dried Yeast	10 mg.	Iodine (Pot. Iodide)	3.12 mg.
B2	2.4 mg.	Wheat Germ Oil	10 mg.	Copper Sulfate	3.25 mg.
B6	0.6 mg.	Biotin	3 mcg.	Manganese Sulf.	3.05 mg.
B12	1.5 mcg.	Choline Bitar.	5 mg.	Magnesium Sulf.	5 mg.
E	3 u.s.	Diesl. Phosp.	110 mg.	Para-Amino-Benzoic Acid	5 mg.
Cal. Pan.	3.5 mg.				

Also Available 003-5540 100—.85 10x100—8.00

		1M	5x1M
DECONGEST Tabs (White) (Similar to Dristan) (100—.95)		8.75	
003-5710	Phenylephrine Hcl. 5 mg. — Phenindamine Tartrate 10 mg. — Aspirin, Caffeine — Alum. Hydroxide — Magnesium Carb. Co-dried gel.		
DECONGESTIVE T.D. Caps 003-5720 (250—5.05)		19.50	
003-5721	Chlorpheniramine Maleate 8 mg. Phenylephrine Hcl. 20 mg. Methacopolamine Nitrate 2.5 mg.		
DEGENEX Caps (Similar to Ornex) 003-5740 (100—1.65)		12.95	
003-5745	Acetaminophen 325 mg. Phenylpropanolamine Hcl. 18 mg.		
Dehydrocholic Acid Tabs			
003-5790	3¾ gr. (White)	27.85	
003-5780	3¾ gr. w/Belladonna Alk. (White)	28.90	
DEXAMETHASONE			
003-5830	0.75 mg. Tabs (Green) (100—2.25)	18.90	
003-5840	1.5 mg. Tabs (Pink) (100—4.15)		

DARBY Suppliers of Fine Quality Branded Generics for over 35 years

Plaintiff's Exhibit 54

		Size	Price
	Cortisocrin		
123-1750	Cint. 1 oz.	1—	3.00
123-1900	Otic	5cc—	2.10
123-1910	Otic	10cc—	3.00
123-1950	Cortn. Cint. 1/8 oz	1—	1.50
123-1960	Cortn. Susp.	5cc—	2.10
123-2200	Cortone 25 mg. tabs	100—	11.40
173-1210	Cortone 25 mg. cc (10—50.60)	20cc—	5.20
173-1220	Cort-Quin Creme 1/2%—1/8 oz.	1—	2.00
123-1900	Cortril Cint. 1oz.	1—	1.30
207-3400	Coryban-D caps	24—	1.00
237-3483	Co-Salt	8oz—	2.65
236-1830	Cosanyi-DM Cough Syrup	1pt.—	4.85
183-2720	Cotazym caps	100—	5.65
184-0300	Cotazym-B	60—	4.95
184-0410	Cotton Swabs Sterile J&J	175—	.95
329-6380	Co-Tylenol tabs	30—	1.05
144-2432			

135-0909

COUMADIN

5 mg. tabs

100—5.15 1M—48.95

	COUMADIN (Warfarin Sod.)		
138-0100	2 mg. (1M—43.70)	100—	4.60
138-0200	2.5 mg. (1M—43.70)	100—	4.60
138-0500	5 mg. (1M—48.95)	100—	5.15
138-0720	7.5 mg.	100—	6.10
138-0900	10 mg. (1M—70.80)	100—	7.30
242-2800	Creamalin tabs	200—	2.95
179-2430	Crest Toothpaste Family Size	1—	1.15
179-2438	Crest Toothpaste Mint Flav.	1—	1.15
187-2428	Cruex Aerosol	4oz—	1.60
187-2440	Cruex Spray Powder	12oz—	3.35
	CRYSTICILLIN		
223-3325	300 A.S. 10cc. (50—16.50)	10—	3.60
223-0360	600 A.S. 12cc. (50—29.00)	10—	6.25
	CRYSTODIGIN		
158-2150	0.05 mg.	500—	2.55
158-2158	0.1 mg. (5M—30.90)	500—	4.15
158-2220	0.15 mg.	500—	5.45
158-2280	0.2 mg.	500—	6.50
131-2440	Cuprex	30z—	1.50
172-1200	Cuprimine 250 mg. caps	50—	9.80
284-2480	Cuticura Soap Bath Bars	3—	1.50
229-1500	Cyclogesterin Oil	5cc—	5.25
104-2500	Cyclogyl 0.5%	15ml—	4.65
104-3600	Cyclogyl 1.0%	15ml—	5.40
	CYCLOSPASMOL (Cyclandelate)		
144-0100	100 mg. tabs. (500—19.30)	100—	4.00
144-0300	200 mg. caps. (500—39.90)	100—	8.40
144-0288	200 mg. caps	1M—	78.45

CYCLANDELATE

(Similar to Cyclospasmol)

200 mg. capsules

003-5310 100—2.45 003-5315 1M—20.70

169-2300	Cytellin	1pt.—	6.10
172-1160	Cytoferin tabs	100—	3.00
230-2000	Cytomel 5 mcg.	100—	1.80
230-2120	Cytomel 25 mcg. (1M—25.50)	100—	2.70
230-2118	Cytomel 50 mcg.	100—	4.10
169-0725	Cytoxan 25 mg tabs	100—	10.65
169-0750	Cytoxan 50 mg. tabs	100—	18.55

		Size	Price
140-0460	D.B.I. 25 mg. tabs. (1M—52.20)	100—	5.40
140-0440	DBI T.D.C. 50 mg. (1M—116.50)	100—	11.95
140-0470	DBI T.D.C. 100 mg. (500—111.95)	100—	22.75
208-1500	D.H.E. 45 1cc amps	20—	15.00
174-1170	*Dactil w/Pheno tabs	50—	3.25
180-3900	Dainite for night tabs.	100—	7.25
180-1001	Dainite-KI tabs. (500—41.00)	100—	3.90
200-0710	Daimane 15 mg. caps	100—	5.90
200-0715		500—	28.20
200-0730	Daimane 30 mg. caps	100—	6.95
200-0735		500—	33.95
139-0070	Dantrium 25 mg. caps	50—	4.60
139-0080	Dantrium 100 mg. caps	50—	8.90
169-1010	Dara Shampoo	1pt.—	2.70
172-1700	Daranide 50 mg. tabs	100—	7.90
122-2100	Darsprim tabs. (1M—12.90)	100—	1.45
220-2300	Darbid 5 mg. tabs (Isocropamide)	50—	3.90
163-0360	Daricon 10 mg. tabs. (500—51.65)	60—	6.25
163-0370	Daricon-PB tabs	100—	8.95
156-2340	Darvocet-N tabs. (500—20.90)	100—	4.40
156-2347	Darvocet-N 100. (500—39.50)	100—	8.30
156-2360	Darvon 32 mg. (500—16.70)	100—	3.72
156-2450	Darvon Comp-32. (500—17.90)	100—	3.80
156-2400	Darvon 65 mg. (500—31.45)	100—	6.90
156-2500	Darvon Comp-65. (500—31.70)	100—	6.90
156-2510	Darvon ASA caps. (500—33.70)	100—	7.40
156-2310	Darvon-N tabs. (500—35.75)	100—	7.85
156-2329	Darvon-N Susp. 50 mg./5cc	1pt.—	8.40
156-2325	Darvon-N w/A.S.A. (500—36.00)	100—	7.60
113-2900	Datril tabs	100—	1.25
102-0905	Dayalets	250—	7.85
102-0900	Dayalets w/Iron tabs. (250—8.25)	100—	3.50
166-0100	Deaner 25 mg. tabs	100—	6.60
166-0200	Deaner 100 mg. tabs	50—	8.60
	DECADRON (Dexamethasone)		
172-1500	4 mg./cc. (25cc—26.65)	5cc—	5.50
172-2300	4 mg./cc w/Xylocaine	5cc—	5.60
172-2110	L.A. Suspension	5cc—	5.90
172-1690	0.5 mg. tabs	100—	11.20
172-2000	0.75 mg. tabs	50—	13.70
172-1930	4 mg. tabs	50—	21.40
172-2100	Elixir 100cc	1—	3.45
172-2125	Ophth. Oint. 0.05% 3.5 gm.	1—	1.15
172-2150	Ophth. Sol. 0.1% 2.5cc	1—	1.60
172-2175	Respihaler Aerosol	1—	5.15
172-2200	Turbinaire 12.6 gm.	1—	5.45
172-2250	Topical Cream 0.1%	15gm—	2.15
184-0800	Deca-Durabolin Box 4 x 1cc	1—	17.95
184-0900	Deca-Durabolin 50 mg./cc	2cc—	8.20
184-0910	Deca-Durabolin 100 mg./cc	2cc—	14.40
173-2400	Decagesic tabs	100—	7.10
173-2460	Decaspray Topical Aerosol	1—	2.75
133-2030	Decholin Amps 5cc	20—	13.40
133-2030	Decholin tabs. (500—29.25)	100—	8.95
	DECLOMYCIN		
154-4800	150 mg. caps. (100—26.20)	16—	4.25
154-4810	150 mg. tabs. (100—26.15)	16—	4.30
154-4820	300 mg. tabs. (48—22.90)	12—	5.25

PROPOXYPHENE COMPOUND-65

(Similar to Darvon Comp-65)

Red & Grey Caps

004-3830 100—1.80 004-3835 500—6.95

PLAINTIFF'S EXHIBIT 55

DARBY DRUG CO. INC.

Winter - Spring '78

A Small Sample of the Outstanding Values in this issue!

AMPICILLIN TRIHYDRATE
F.D.A. Certified

250 mg. Caps	500 mg. Caps
310-0010	310-0016
100 - 4.75	100 - 9.45
310-0015	310-0018
500 - 22.95	500 - 45.95
310-0013	310-0019
1M - 45.40	2x500 - 91.50

ERYTHROMYCIN STEARATE

250 mg. Tabs			500 mg. Tabs	
310-0250	100	5.55	310-0265	
310-0255	500	26.85	100	11.75

IMIPRAMINE HCl
25 mg. Tabs
(Similar to Tofranil)
003-9305 1M - 20.95

PENICILLIN VK
(Potassium Phenoxymethyl Penicillin)
Oval Shaped Tabs 250 mg.

400-2520	400-2525
100 - 2.35	1M - 20.50

VITAMIN C TABS

		100	1M
003-2880	250 mg.	.85	5.55
003-2920	500 mg.	1.10	8.20

METHYLPREDNISOLONE ACETATE
40 mg./cc
(Similar to Depo-Medrol)
301-5340
5cc - 3.85 10x5cc - 37.40

DEXAMETHASONE PHOSPHATE
4 mg./cc
(Similar to Decadron)
301-4150
5cc - 1.15 10x5cc - 11.05

PREDNISOLONE
Aqueous 25 mg./cc/30cc
301-6410
1 - 1.85 10 - 18.10

HYDRO-CHLOROTHIAZIDE
(Similar to Hydrodiuril) 50 mg Tabs
003-9190 100 — 1.00
003-9192 1M — 4.50

PROPOXYPHENE COMPOUND - 65®
(Similar to Darvon Compound-65)
004-3830 100 — 1.95
004-3832 500 — 7.70
004-3834 1M — 14.70

CHLORDIAZEPOXIDE HCl®
(Similar to Librium)
10 mg. Caps (Black/Green)
003-4880 100 — 1.40
003-4882 500 — 4.85
003-4885 1M — 9.15

TETRACYCLINE HCl
F.D.A. Certified U.S.P.
250 mg. Caps (Orange & Yellow)

310-1820	310-1825
100 — 1.80	1M — 14.45

500 mg. Caps (Black & Yellow)

310-1870	310-1875
100 — 3.15	1M — 26.85

VITAMIN B-12
(Crystalline)
100 mcg./cc

300-2040	10	50
10cc vials	4.20	20.00
300-2060		
30cc vials	5.70	27.50

STERILE DISPOSABLE SYRINGES
3cc W/NEEDLE

			100
321-1040 25 x ⅝	321-1030 22 x 1¼	321-1010 21 x 1	6.40
321-1035 23 x 1	321-1025 22 x 1½	321-1005 20 x 1½	1000
321-1020 22 x 1	321-1015 21 x 1½	321-1000 20 x 1	

MANUFACTURED IN U.S.A.

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PLAINTIFF'S EXHIBIT 55

Plaintiff's Exhibit 55

Tablets/Capsules

IMPORTANT! Please add Stock No. when ordering

				1M	5x1M
CHLORPROMAZINE (Similar to Thorazine)					
10 mg. Tabs S.C. (Rust)	003-4545	100—1.10	003-4547	7.10	
25 mg. Tabs S.C. (Rust)	003-4550	100—1.35	003-4551	9.25	
50 mg. Tabs S.C. (Rust)	003-4560	100—1.75	003-4561	13.20	
100 mg. Tabs S.C. (Rust)	003-4570	100—2.75	003-4572	22.85	
200 mg. Tabs S.C. (Rust)	003-4580	100—3.80	003-4586	33.90	
COLCHICINE Tabs 0.6 mg. (1/100 gr.) (White)			003-4940	9.30	43.95
Cold Tabs #1 (Red) — Chlorpheniramine Maleate 2 mg.; Phenylephrine HCl 4 mg.; Phenacetin 162.5 mg.; Caffeine 32.4 mg.			003-4960	7.75	37.90
Cold Tabs #2 (Purple) — Phenylarocanolamine HCl 25 mg.; Chlorpheniramine Maleate 2 mg.; Pyrilamine Maleate 10 mg.; Terpin Hydrate 2½ gr.; Acetaminophen 5 gr.			Salicylamide		227.5 mg.
			003-5000	9.65	47.25
Cold Tabs #2 with DMH (Rose) — Phenylarocanolamine HCl 25 mg.; Chlorpheniramine Maleate 2.5 mg.; Pyrilamine Maleate 10 mg.; Terpin Hydrate 162 mg.; Acetaminophen 325 mg.; Dextromethorphan H Br 7½ mg.			003-5010	15.50	75.25
Cold Capsules—Mild (Yellow/Blue) — Aspirin 227 mg.; Phenacetin 162 mg.; Pyrilamine Maleate 10 mg.; Caffeine 32.5 mg.			003-5040	8.75	42.50
Cold Capsules—Medium (Yellow/Purple) — Aspirin 162 mg.; Phenacetin 162 mg.; Caffeine 32.4 mg.; Pyrilamine Maleate 25 mg.			003-5060	11.50	56.50
Cold Capsules—Forte (Brown/White) — Aspirin 2½ gr.; Phenacetin 1½ gr.; Quinine Sulfate ¼ gr.; Atropine Sulfate 1/1000 gr.; Camphor ½ gr.; Podophyllum 1/60 gr.; Alein 1/10 gr.			003-5080	10.90	53.20
Conjugated Estrogens U.S.P.					
0.625 mg. Tabs (Maroon)	003-5160	100—2.05	003-5161	17.50	
1.25 mg. Tabs (Yellow)	003-5220	100—3.40	003-5221	30.70	
2.50 mg. Tabs (Purple)	003-5290	100—5.70	003-5295	53.35	
Cortisone Tablets 25 mg. (White)	003-5300	100—3.75	003-5300	34.90	
Cough Wafers Mentholated — Benzocaine ½ gr. — Licorice P.E. 1/16 gr. Oil of Anise, Eucalyptol and Menthol			003-5340	2.75	12.95
CYCLANDELATE (Similar to Cyclospasmol)					
200 mg. Caps (Blue)	003-5310	100—1.75	003-5315	13.95	
400 mg. Caps	003-5290	100—3.45	003-5293	500—14.95	
CYTOMINE® Tabs (Similar to Cytomel)					
25 mcg. (White)	003-5330	100—1.10	003-5335	7.45	
50 mcg. (White)	003-5355	100—1.15	003-5357	8.95	

ONE OF AMERICA'S MOST POPULAR GENERIC FORMULAS

DARLITE®

				1M	5x1M
Capsule Shaped Tabs (S.C. Brown)			003-5341	7.25	34.95
D 400 I.u.	Niacinamide 12 mg	Inositol 5 mg.			
A 5,000 I.u.	Pot. Sulfate 6 mg.	Phosphorous 85 mg.			
C 60 mg.	Zinc Sulfate 0.2 mg.	Ferrous Sulf. 12 mg.			
B1 3.5 mg.	Dried Yeast 10 mg.	Iodine (Pot. Iodide) 0.12 mg.			
B2 2.4 mg.	Wheat Germ Oil 10 mg.	Copper Sulfate 0.05 mg.			
B6 0.6 mg.	Biotin 3 mcg.	Manganese Sulf. 0.05 mg.			
B12 1.5 mcg.	Choline Bitar. 5 mg.	Magnesium Sulf. 5 mg.			
E 3 I.u.	Dical. Phosp. 110 mg.	Para-Amino-Benzoic Acid 5 mg.			
Cal. Pen. 3.5 mg.					
Also Available	003-5340	100—.90	10x100—8.55		

Plaintiff's Exhibit 55

C-D

GENERIC GUIDE Section

DARBY

NAME BRAND

CYCLOSPASMOL
200 MG. CAPS
Ives
144-0200 100— 8.40

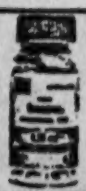
CYTOMEL
(Sod. Liothyronine)
S.K.F.
25 MCG. TABS
220-2100 100— 2.70
220-2105 1M—25.50
50 MCG. TABS
220-2115 100— 4.10

DARVON ®
65 MG. PULVULES
(Propoxyphene HCl)
Lilly
158-2400 100— 6.95
158-2405 500—33.80

DARVON ®
COMP-65
Lilly

Propoxyphene HCl	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg.

158-2500 100— 7.25
158-2505 500—34.20



DECADRON
0.75 MG. TABS
(Dexamethasone)
Merck
172-2000 100—14.50

DECHOLIN TABS
(Dehydrocholic Acid 250 mg.)
Dome
132-2020 100— 6.55
132-2025 500—31.70

DELTASONE
5 MG. TABS
(Prednisone)
Upjohn
228-2100 100—2.30

"BRANDED GENERICS" by DARBY

ORDER BY NUMBER PLEASE

CYCLANDELATE
200 MG. CAPS
Darby
003-5310 100— 1.75
003-5315 1M—13.95

CYTOMINE™
(Sod. Liothyronine)
Darby
25 MCG. TABS
003-5330 100—1.10
003-5335 1M—7.45
50 MCG. TABS
003-5355 100—1.15
003-5357 1M—8.95

PROPOXYPHENE HCl ®
65 MG. CAPSULES
Darby
004-3820 100—1.65
004-3822 500—6.10

PROPOXYPHENE ®
COMP-65
Darby

Propoxyphene HCl	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg.

004-3830 100— 1.95
004-3832 500— 7.70
004-3834 1M—14.70

DEXAMETHASONE
0.75 MG. TABS
Darby
003-5830 100— 3.80
003-5830 10x100—36.30

DEHYDROCHOLIC ACID
250 MG. TABS
Darby
003-5790 1M—27.85

PREDNISONE
5 MG. TABS
Darby
004-3242 1M—7.40

IMPORTANT! Please add Stock No. when ordering

C (Continued)

Plaintiff's Exhibit 55

C (Continued)

		Size	Price
	CORDRAN-N		
188-2080	Cream	15gm—	2.75
188-2088	Cream	60gm—	7.95
188-2100	Oint.	15gm—	2.75
188-2108	Oint.	60gm—	7.95
188-2118	Cordran Tape (Large)	1—	6.15
107-2428	Corega Dent. Adhes. Pdr. 3.5 oz.	1—	1.70
	CORICIDIN		
214-1200	tabs. (1M—23.50)	100—	2.55
214-1230	Industrial Pack tabs	400—	8.40
214-1240	Demilets Pediatric	36—	.85
214-1300	Forte caps	100—	6.35
214-1400	Medilets Pediatric	36—	.70
214-1500	Nasal Mist	20cc—	1.00
214-1700	"D" Decongestant tabs	100—	3.10

COUMADIN
5 mg. tablet
100—5.60 1M—53.20

138-0330	Cort-Acne lotion	1oz—	2.30
138-0364	Cort-Acne lotion	2oz—	3.40
	COR-TAR-QUIN CREME		
133-1600	¼%—Tube	4oz—	5.75
133-1300	½%—½ oz. Tube	1—	2.65
	CORT-DOME CREME		
133-0600	¼%—Tube	1oz—	1.70
133-0800	¼%—Tube	4oz—	4.30
133-0800	½%—½ oz. Tube	1—	1.70
133-0805	½%—Tube	1oz—	2.90
133-0808	1%—Tube	1oz—	5.20
	CORT-DOME LOTION		
133-1110	½%	4oz—	4.50
264-9429	Corteneme 60cc (Box 7)	1—	11.45
	Cortisporin		
133-1700	Oint. ½ oz.	1—	3.00
133-1810	Otic	10cc—	3.00
133-1830	Otic Suspension	10cc—	3.00
133-1900	Ophth. Oint. 1/8 oz.	1—	1.50
133-2000	Ophth. Susp.	5cc—	2.10
173-1210	Cortone 25 mg. tabs	100—	13.05
173-1230	Cortone 25 mg./cc. (10—50.60)	20cc—	5.20
337-0400	Cortril Oint. ½ oz.	1—	1.50
337-0440	Coryban-D caps	24—	1.00
188-2800	Co-Salt	8oz—	2.65
184-0300	Cotazym caps	100—	6.35
184-0410	Cotazym-S	60—	5.25
325-6280	Cotton Swabs J&J	175—	1.15
184-9436	Co-Tylenol tabs	48—	2.15
	COUMADIN (Warfarin Sod.)		
138-0100	2 mg	100—	5.05
138-0300	2.5 mg	100—	5.05
138-0600	5 mg. (1M—53.20)	100—	5.60
138-0700	7.5 mg	100—	6.80
138-0800	10 mg. (1M—76.95)	100—	8.10
340-0800	Creamalin tabs.	200—	3.55
178-9430	Crest Toothpaste Family Size	1—	1.25
178-9436	Crest Toothpaste Mint Flav	1—	1.25
187-9438	Cruex Spray Powder	4oz—	1.60
187-9440	Cruex Spray Powder	12oz—	3.35
	CRYSTICILLIN		
223-0388	300 A.S. 10cc. (50—37.20)	10—	7.90
223-0360	600 A.S. 12cc. (50—72.60)	10—	15.20
	CRYSTODIGIN		
188-2150	0.05 mg.	500—	2.80
188-2155	0.1 mg. (5M—35.85)	500—	4.55
188-2200	0.15 mg.	500—	5.95

DEA NO. REQUIRED

		Size	Price
108-2900	Cuprex	3oz—	2.10
173-1305	Cuprimine 250 mg. caps	100—	21.95
254-2480	Cuticura Soap Bath Bars	3—	1.65
228-1500	Cyclogesterin Oil	5cc—	5.75
104-2500	Cyclogyl 0.5%	15ml—	5.50
104-2600	Cyclogyl 1.0%	15ml—	6.25
	CYCLOSPASMOL (Cyclandelate)		
144-0100	100 mg. tabs. (500—19.50)	100—	4.20
144-0900	200 mg. caps. (500—39.90)	100—	8.40
156-2300	Cytellin	1pt.—	6.10
230-2000	Cytomel 5 mcg.	100—	1.80
230-2100	Cytomel 25 mcg. (1M—25.50)	100—	2.70
230-2115	Cytomel 50 mcg.	100—	4.10
168-0725	Cytoxan 25 mg tabs	100—	12.70
168-0750	Cytoxan 50 mg. tabs	100—	23.35

D

208-1500	D.H.E. 45 1cc amps	20—	16.80
215-0400	Decriose Sol.	4oz—	2.00
174-1170	Dectil w/Pheno tabs	50—	3.65
160-1091	Dainite-KI tabs. (500—49.70)	100—	10.80
200-0710	Daimane 15 mg. caps. CIV	100—	8.45
200-0715	CIV	500—	40.95
200-0730	Daimane 30 mg. caps. CIV	100—	10.15
200-0735	CIV	500—	49.55
242-0600	Danocrine 200 mg caps.	100—	97.50
136-0072	Dantrium 25 mg. caps.	100—	10.60
136-0082	Dantrium 100 mg. caps	100—	18.50
165-1010	Dara Shampoo	1pt.—	2.90
173-1700	Daranide 50 mg. tabs	100—	8.90
122-2100	Daraprim tabs.	100—	1.45
220-1300	Darbid 5 mg. tabs (Isopropamice)	50—	3.90
142-0360	Daricon 10 mg. tabs. (500—52.60)	60—	6.45
142-0370	Daricon-PB tabs	100—	9.30
156-2340	Darvocet-N tabs. CIV	100—	4.70
156-2348	CIV	500—	22.75
156-2347	Darvocet-N 100 tabs. CIV	100—	8.85
156-2348	CIV	500—	43.20
156-2350	Darvon 32 mg. CIV	100—	3.80
156-2358	CIV	500—	17.95
156-2460	Darvon Comp-32. CIV	100—	4.00
156-2468	CIV	500—	19.20
156-2400	Darvon 65 mg. CIV	100—	6.95
156-2408	CIV	500—	33.80
156-2500	Darvon Comp-65. CIV	100—	7.25
156-2508	CIV	500—	34.20
156-2510	Darvon ASA caps. CIV	100—	7.20
156-2515	CIV	500—	35.40
156-2310	Darvon-N tabs. CIV	100—	8.05
156-2316	CIV	500—	39.70
156-2329	Darvon-N Susp. 50 mg/5cc. CIV	1pt—	5.40
156-2325	Darvon-N w/A.S.A. CIV	100—	8.15
156-2330	CIV	500—	39.45
113-2900	Datril tabs	100—	1.60
113-2610	Datril 500 X-Strength caps	72—	1.50

PROPOXYPHENE COMPOUND-65
(Similar to Darvon Comp-65)
Red & Grey Caps
100—1.95 500—7.70

641a

PLAINTIFF'S EXHIBIT 56

Sherry SPRING 1978

MEDICAL/SURGICAL SUPPLY CATALOG

NEW PRODUCT

ISOPRO
(Comparable to Combid)
Time Release Caps

003-9570 100 — 5.20
003-9572 500 — 23.90

A SHERRY EXCLUSIVE!

METHOCARBAMOL W/ASA
(Comparable to Robaxisal)
Multi-Layered Tab Pink/White

004-0280 100 — 2.70
004-0282 500 — 11.50
004-0285 1M — 21.40

AMPICILLIN TRIHYDRATE
F.D.A. Certified
250 mg. Maroon & Grey Caps

310-0010 1x100 4.70
310-0015 1x500 22.75
310-0013 1x1000 44.95

HYDRO-CHLOROTHIAZIDE
(Comparable to Hydrodiuril)
50 mg. Tabs

003-9190 1x100 .95
003-9192 1x1000 4.50

PROPOXYPHENE COMPOUND 65 CIV
(Comparable to Darvon Compound-65)

004-3830 1x100 1.95
004-3832 1x500 7.70
004-3834 1x1000 14.70

CHLOR-DIAZEPOXIDE HCl CIV (Comparable to Librium)
10 mg. Black/Green Caps

003-4880 1x100 1.30
003-4882 1x500 4.75
003-4885 1x1000 8.50

VITAMIN E
dl-alpha tocophery
200 I.U. Soft Gelatin Caps

004-7995 1x100 2.10
004-7996 1M 18.95

TETRACYCLINE HCl

F.D.A. Certified U.S.P.
250 mg. Orange & Yellow Caps

310-1820 1x100 1.75
310-1825 1x1000 14.25

VITAMIN B12
1000 mcg/cc (Crystalline)
10cc Vials

300-2040 10 Vials 3.85
300-2040 50 Vials 17.95
30cc Vials
300-2060 10 Vials 5.50
300-2060 50 Vials 26.90

PAPAVERINE HCl
150 mg.
Brown & Clear I.D. Caps

004-1248 1x100 2.05
004-1247 1x1000 16.25

YOURS FREE!
TELEPHONE INDEX
with every order of $75.00 or more! Smartly designed in contemporary brushed steel and heavy vinyl. A must for every busy professional.

000-1701

PLAINTIFF'S EXHIBIT

Plaintiff's Exhibit 56

GENERIC TABLETS and CAPSULES

IMPORTANT: PLEASE USE PRODUCT NUMBERS WHEN ORDERING

QUININE SULFATE Caps. U.S.P. 325 mg.	004-4332	100	8.40
	004-4333	1M	78.30
RAUWOLFIA SERPENTIA, N.F.			
(Comparable to Raudixin)			
100 mg. S. C. Red Tabs	004-4400	1M	7.45
	004-4401	1x5M	36.50
RESERPINE U.S.P.			
(Comparable to Serpasil)			
0.1 mg. Tabs	004-4540	1M	1.25
	004-4541	1x5M	5.55
0.25 mg. Tabs	004-4580	1M	1.30
	004-4581	1x5M	5.50

SPASMOL

Comparable to Cyclospasmol

200 mg. Blue Capsules

003-5310 1x100 **1.70** 003-5315 1x1000 **13.75**

R-H-H Pink Tabs	004-7210	100	2.05
(Comparable to Ser-Ap-Es)	004-7212	1M	16.95
Each pink tab contains: Reserpine 0.1 mg., Hydralazine 25 mg., Hydrochlorothiazide 15 mg.			
SACCHARIN U.S.P.			
¼ gr. White Tabs	004-5080	1M	.80
	004-5085	5x1M	3.75
½ gr. White Tabs	004-5100	1M	1.25
	004-5105	5x1M	6.00
SENACTIN Tabs	004-5290	100	.75
(Comparable to Senokot)	004-5295	1M	3.65
Each tab contains: Standardized Extract of Senna Fruit 217 mg.			
SHERDECON Tabs	004-7250	100	1.65
(Comparable to Naldecon)	004-7257	1M	13.60
SHERFACT Tabs	003-0180	100	1.30
(Comparable to Actifed)	003-0185	1M	9.45
Each tab contains: Tripolidine HCl 2.5 mg., Pseudoephedrine HCl 60 mg.			

SHERDECON Tabs

Comparable to Naldecon

004-7250 1x100 **1.65**

004-7257 1x1000 **13.60**

SHERRYLAC Tabs	003-4301	1M	3.00
(Comparable to Titralac)	003-4305	5x1M	14.40
Each tab contains: Calcium Carbonate 0.42 gm., Glycine 0.18 gm.			
SIN-A-PAP Tabs	004-1580	100	1.10
(Comparable to Sinutabs)	004-1581	1M	7.45
Each pink tab contains: APAP 150 mg., Phenyltoloxamine 22 mg., Phenacetin 150 mg., Phenylpropanolamine HCl 25 mg.	004-1585	5x1M	36.95
SINEZE Caps *(Comparable to Ornex)*	003-5740	100	1.65
Each blue & white cap contains: APAP 325 mg., Phenylpropanolamine HCl 18 mg.	003-5745	1M	12.95
SINO-CLEAR Multilayer Tabs	004-5360	1M	9.70
Prompt Relief of Colds, Hay Fever, Sinus	004-5365	5x1M	46.95
Each tab contains: Caffeine 10 mg., Chlorpheniramine Mal. 2 mg., Phenacetin 100 mg., Phenylephrine HCl 5 mg., Salicylamide 227 mg.			
SODIUM FLUORIDE			
2.2 mg. White Tabs	004-5480	1M	1.35
	004-5485	5x1M	7.10
2.2 mg. Chewable, Flavored Tabs	004-5490	1M	1.45
	004-5495	5x1M	7.75
SODIUM SALICYLATE U.S.P.			
5 gr. E. C. Red Tabs	004-5600	1M	3.25
	004-5605	5x1M	23.50
10 gr. E. C. Red Tabs	004-5620	1M	8.35
	004-5625	5x1M	41.75
SPASMOL Caps			
(Comparable to Cyclospasmol)			
200 mg. Blue Caps	003-5310	100	1.70
	003-5315	1M	13.75
400 mg. Red/Blue Caps	003-5290	100	3.10
	003-5295	500	13.80
SPASMTABS	003-9200	1M	2.25
(Comparable to Donnatal)	003-9201	1x5M	8.25
Each white tab contains: Atropine Sulfate 0.0194 mg., Hyoscine HBr .0065 mg., Hyoscyamine SO. 0.1037 mg., Phenobarbital ¼ gr.			

SHERFACT

Comparable to Actifed

White Tablets

003-0180 1x100 **1.30** 003-0185 1x1000 **9.45**

SPASTOLATE Caps	003-9260	1M	8.05
(Comparable to Donnatal)	003-9265	5x1M	39.10
Each green & clear cap contains: Atropine Sulfate 0.0194 mg., Hyoscine HBr .0065 mg., Hyoscyamine SO. 0.1037 mg., Phenobarbital 16.2 mg.			
STILBESTROL Tabs U.S.P.			
1.0 mg. White C. T.	004-5840	1M	6.10
	004-5845	5x1M	29.70
1.0 mg. Red E. C.	004-5860	1M	9.10
	004-5865	5x1M	44.25
5 mg. White C. T.	004-5880	1M	8.95
	004-5885	5x1M	43.50
5 mg. Red E. C.	004-5900	1M	11.95
	004-5905	5x1M	58.50
SULFADIAZINE Tabs 7.7 gr.	004-6060	1M	17.50
SULFAMETHOXAZOLE Tabs. 0.5 gm.	004-6120	100	4.85
(Comparable to Gantanol)			
SULFASALAZINE Gold Tabs 500 mg.	004-6170	100	3.85
(Comparable to Azulfidine)	004-6175	500	16.90
SULFISOXAZOLE White Tabs. 0.5 gm.	004-6181	1M	14.95
(Comparable to Gantrisin)			

QUINIDINE

200 mg. U.S.P.

004-4325 1x100 — **6.60**

004-4329 1x1M — **55.50**

For CIII, CIV, CV, DEA Registry # Required

IMPORTANT: PLEASE USE PRODUCT NUMBERS WHEN ORDERING

156-1800	CO-PYRONIL Caps. 100		1	7.65
156-1805	Caps. 1000		1	68.50
	CORDRAN			
156-1902	Cream, 7½ gm., 0.5%		1	1.55
156-1900	Cream, 15 gm., 0.5%		1	2.45
156-1905	Cream, 60 gm., 0.5%		1	6.95
156-2010	½ Strength Cream, 60 gm.		1	3.75
156-2005	0.05% Lotion, 60cc		1	6.95
156-1950	Ointment, 15 gm., 0.5%		1	2.45
156-1955	Ointment, 60 gm., 0.5%		1	6.95
156-2015	½ Strength Oint., 60 gm.		1	3.75
156-2115	Tape, 80" x 3"		1	6.45
	CORDRAN-N			
156-2050	Cream, 15 gm.		1	2.65
156-2055	Cream, 60 gm.		1	7.95
156-2100	Ointment, 15 gm.		1	2.65
156-2105	Ointment, 60 gm.		1	7.95
	CORICIDIN			
214-1700	"D" Tabs, 100		1	3.10
214-1705	"D" Indust. Pack, 400		1	8.70
214-1242	Demilets, 24		6	4.20
214-1200	• Tabs. 100		1	2.50
214-1220	Tabs. Indust. Pack, 400		1	7.90

DIPHTHERIA PERTUSSIS TETANUS TOXOID

Alum Precipitate, 7.5cc Vial

174-1260 1 Vial **2.15**

174-1260 10 Vials **19.95**

214-1300	CORIFORTE Caps. 100		1	7.80
128-0305	CORT-ACNE Lot., 2 oz.		1	3.35
	COR-TAR-QUIN			
132-1310	½% Creme, 1 oz.		1	2.60
	CORT-DOME			
132-0500	• ½% Creme, 1 oz.		1	1.70
132-0505	• 1% Creme, 1 oz.		1	2.90
254-2429	CORTENEMA, 7x60cc		1	11.45
	CORTISPORIN			
122-1700	Ointment, ½ oz.		1	3.00
122-1900	Ophth. Oint., ⅛ oz.		1	1.50
122-2000	Ophth. Susp., 5cc		1	2.10
122-1810	Otic Drops, 10cc		1	3.00
122-1820	Otic Suspension, 10cc		1	3.00
166-2500	CO-SALT, 8 oz.		1	2.75
	COTAZYM			
184-0300	Caps. 100		1	6.20
184-0305	Caps. 500		1	29.45
184-2435	CO-TYLENOL Tabs. 48		1	2.15
	COUMADIN (Warfarin)			
138-0100	2 mg. Tabs. 100		1	5.00
138-0300	2½ mg. Tabs. 100		1	5.05
138-0500	5 mg. Tabs. 100		1	5.45
138-0600	5 mg. Tabs. 1000		1	52.75
138-0700	7½ mg. Tabs. 100		1	6.70
138-0900	10 mg. Tabs. 100		1	7.95
343-0800	CREAMALIN Tabs. 200		1	3.90
	CRUEX			
187-3435	Spray Powder, 4 oz.		1	1.80
187-2430	Medicated Cream, 15 gm.		1	1.35
	CRYSTICILLIN (Procaine Penicillin G)			
222-0325	300,000 U.S. 10cc	10		7.90
222-0325	300,000 U.S. 10cc	100		72.50
222-0350	600,000 U.S. 12cc	10		15.20
222-0350	600,000 U.S. 12cc	100		141.25
	CRYSTODIGIN (Digitoxin)			
184-2133	• 0.1 mg. Tabs. 100		1	1.25
	CU-7			
212-0775	Copper Intrauterine, 6		1	63.95
212-0775	Copper Intrauterine, 6		5	315.95
230-1200	C.V.P. Caps. 100		1	7.95
230-1205	Caps. 500		1	35.95
	CYCLAINE HCl (Hexylcaine HCl)			
172-1450	5% Topical, 60cc		1	3.20
	CYCLOGYL			
104-2500	0.5% Ophth. Sol., 15cc		1	5.50
104-2600	1% Ophth. Sol., 15cc		1	6.25
	CYCLOSPASMOL (Cyclandelate)			
144-0100	100 mg. Tabs. 100		1	4.20
144-0200	• 200 mg. Caps. 100		1	8.00
	CYTOMEL (Liothyronine)			
220-2000	5 mcg. Tabs. 100		1	1.80
220-2100	• 25 mcg. Tabs. 100		1	2.70
220-2105	• 25 mcg. Tabs. 1000		1	25.50
220-2115	• 50 mcg. Tabs. 100		1	4.10
	CYTOXAN			
168-0750	50 mg. Tabs. 100		1	23.35

D

219-0400	DACRIOSE Sol. 4 oz.		1	2.00
	DALMANE (Flurazepam HCl)			
200-0710	15 mg. Caps. 100	CIV	1	8.45
200-0715	15 mg. Caps. 500	CIV	1	40.95
200-0730	30 mg. Caps. 100	CIV	1	16.15
200-0735	30 mg. Caps. 500	CIV	1	48.55
	DANOCRINE			
242-0900	200 mg. Caps. 100		1	97.50
	DANTRIUM			
136-0072	25 mg. Caps. 100		1	10.60
136-0082	100 mg. Caps. 100		1	18.50
172-1700	DARANIDE Tabs. 100		1	5.90
	DARICON			
162-0360	10 mg. Tabs. 60		1	6.40
162-0365	10 mg. Tabs. 500		1	32.60
156-2340	DARVOCET-N Tabs. 100	CIV	1	8.05
156-2345	Tabs. 500	CIV	1	24.35
	DARVOCET-N 100			
156-2347	Tabs. 100	CIV	1	9.50
156-2348	Tabs. 500	CIV	1	44.90
	DARVON (Propoxyphene HCl)			
156-2350	32 mg. Caps. 100	CIV	1	4.05
156-2355	32 mg. Caps. 500	CIV	1	19.55
156-2400	• 65 mg. Caps. 100	CIV	1	7.15
156-2405	• 65 mg. Caps. 500	CIV	1	33.20
	DARVON COMPOUND			
156-2450	Caps. 100	CIV	1	4.25
156-2455	Caps. 500	CIV	1	21.10
156-2500	• '65' Caps. 100	CIV	1	7.45
156-2505	• '65' Caps. 500	CIV	1	35.80
	DARVON-N CIV (Propoxyphene Napsylate)			
156-2310	100 mg. Tabs. 100		1	8.70
	DARVON-w/A.S.A.			
156-2510	Caps. 100	CIV	1	7.75
156-2515	Caps. 500	CIV	1	36.25

COMBISTIX Strips

108-0900 1 x 100 **10.25**

108-0900 10 x 100 **101.40**

	DARVON-N w/A.S.A.			
156-2325	Tabs. 100	CIV	1	8.75
156-2330	Tabs. 500	CIV	1	42.95
	DAXOLIN			
132-1950	10 mg. Caps. 100		1	10.90
132-1960	25 mg. Caps. 100		1	16.50
132-1970	50 mg. Caps. 100		1	21.90
198-0220	DEANER-250 Tabs. 50		1	15.40
	DEBRISAN POWDER			
191-0800	7x4 gm. Packets		1	14.80
191-0805	14x4 gm. Packets		1	32.40
191-0810	60 gm. Container		1	32.40
191-0815	120 gm. Container		1	62.40
254-2325	DEBROX Drops, 15cc		1	1.65
	DECA-DURABOLIN (Nandrolone Decanoate)			
184-0900	50 mg./cc Vial, 2cc		1	8.75
184-0800	50 mg./cc Vial, 4 x 1cc		1	19.20
184-0910	100 mg./cc Vial, 2cc		1	16.20
	DECADRON (Dexamethasone)			
172-2100	• Elixir, 100cc		1	3.65
172-1900	• 4 mg./cc Injection, 5cc		1	5.50
172-1900	• 4 mg./cc Injection, 5cc		10	53.30
172-1903	• 4 mg./cc Injection, 25cc		1	26.65
172-2150	0.1% Ophth. Sol., 2.5cc		1	1.80
172-2155	0.1% Ophth. Sol., 5cc		1	3.15
172-1950	0.5 mg. Tabs. 100		1	11.65
172-2000	• 0.75 mg. Tabs. 100		1	14.50
172-2250	0.1% Top. Cream, 15 gm.		1	2.40
172-2200	Turbinaire 12.6 gm.		1	6.15

DECADRON

4 mg/cc, 5cc Vial

172-1900 1 Vial **5.50**

172-1900 10 Vials **53.30**

	DECADRON w/XYLOCAINE			
172-2300	Injection, 5cc		1	5.60
172-2300	Injection, 5cc		10	54.40
172-2400	DECAGESIC Tabs. 100		1	7.45
	DECLOMYCIN			
154-4500	150 mg. Caps. 16		1	5.05
154-4505	150 mg. Caps. 100		1	30.50
154-4605	Syrup, 16 oz.		1	18.95
	DECLOSTATIN			
154-5000	Caps. 16		1	5.85
154-5005	Caps. 100		1	35.15
	DECONAMINE			
219-0440	Caps. 100		1	10.90
	DELADUMONE			
222-0400	• Vial, 5cc		1	4.70
222-0400	• Vial, 5cc		5	21.95
	DELADUMONE OB			
222-0425	• Vial, 2cc		1	5.10
222-0425	• Vial, 2cc		10	48.50
	DELALUTIN (Hydroxyprogesterone Caproate)			
222-0500	• 125 mg./cc Vial, 10cc		1	9.00
222-0500	• 125 mg./cc Vial, 10cc		5	42.65
222-0600	• 250 mg./cc Vial, 5cc		1	8.10
222-0600	• 250 mg./cc Vial, 5cc		5	38.40
	DELATESTRYL (Testosterone Enanthanate)			
222-0700	• 200 mg./cc Vial, 5cc		1	7.50
	DELESTROGEN (Estradiol Valerate)			
222-0800	• 10 mg./cc Vial, 5cc		1	4.40
222-0800	• 10 mg./cc Vial, 5cc		5	20.75
222-0900	• 20 mg./cc Vial, 5cc		1	6.10
222-0900	• 20 mg./cc Vial, 5cc		5	28.95
222-1000	• 40 mg./cc Vial, 5cc		1	10.20
222-1000	• 40 mg./cc Vial, 5cc		5	48.20

• Generics Available on Pages 4-32

For CIII, CIV, CV, DEA Registry # Required

PLAINTIFF'S EXHIBIT 57

RUGBY

LABORATORIES Inc.

20 Nassau Avenue
Rockville Centre, L.I., N.Y. 11570

"A Full Line of GENERICS"

ORDER WITH CONFIDENCE FROM

RXS
PLF. Oshkin
EX. 1
WIT.
DATE May 9 1977
BAR ASSOCIATION REPORTING SERVICE

PLAINTIFF'S EXHIBIT 57

"YOUR RUGBY DISTRIBUTOR"

Plaintiff's Exhibit 57

RUGBY LABORATORIES Inc.

HANDY BRAND AND GENERIC REFERENCE

NATIONAL BRAND	RUGBY GENERIC BRAND	PAGE
ACHROMYCIN-V	TETRACYCLINE	
Caps	Caps	15
Syrup	Syrup	23
ACTIFED	ALLERFRIN	
Tabs	Tabs	6
Syrup	Syrup	21
ADEFLOR	VITAFLOR	19
ALLBEE w/C	VITABEE w/C	19
ALLBEE-T	VITABEE-T	19
AMBENYL	BROMOTUSS	21
AMCILL	AMPICILLIN	
Caps	Caps	6
Suspension	Suspension	21
AMESEC	AMO-FED	6
ANTABUSE	DISULFIRAM	10
ANTEPAR	PIPERAZINE TART.	13
ANTIVERT	MECLIZINE	11
APRESOLINE	HYDRALAZINE	10
APRESOLINE-ESIDRIX	APRESODEX	6
AQUASOL E	VITAMIN E	17
ARISTOCORT	TRIAMCINOLONE	15, 23
ARLIDIN	NYLIDRIN	12
ARTANE	TRIHEXANE	16
ASCRIPTIN	BUFFERED ASPIRIN	7
AZO-GANTRISIN	AZO-SULFISOXAZOLE	7
AZULFIDINE	SULFASALAZINE	15
BECOTIN-T	BEE-T-VITES	19
BECOTIN w/C	VI-C-TINIC w/C	19
BEMINAL FORTE WITH C	BEE-FORTE WITH C	19
BENADRYL	DIPHENHYDRAMINE	
Caps	Caps	10
Elixir	Elixir	21
BENEMID	PROBENECID	13
BENTYL	BENTOMINE	7
BENYLIN	DIPHENHYDRAMINE	10
BETADINE	POVIDINE	
	Solution	22
	Surgical Scrub	22

NATIONAL BRAND	RUGBY GENERIC BRAND	PAGE
BONINE	MECLIZINE	11
BUFFERIN	BUFFERED ASPIRIN	7
BUTIBEL	BUTABARB-BELLADONNA	7
BUTISOL	BUTABARBITAL	7
CVP	BIOFLAVANOIDS #1	19
CAFERGOT	ERGO-CAFF	10
CHLOROMYCETIN	CHLORAMPHENICOL	8
CHLORTRIMETON	CHLORPHENIRAMINE MAL.	8
CHOCKS	CHEWABLE-VITE	19
CHOCKS w/IRON	CHEWABLE-VITE w/IRON	19
COLACE	DIOCTYL SODIUM SULFOSUCCINATE	9, 21
COLBENEMID	PROBEN-C	13
COMBID	ISOPRO	11
COMPOCILLIN VK	PENICILLIN-VK	13
CORICIDIN	CHLORPHENIRAMINE	8
CRYSTODIGIN	DIGITOXIN	9
CYCLOSPASMOL	CYCLANDELATE	9
CYTOMEL	CYTOMINE	9
DARVON	PROPOXYPHENE HCl	14
DARVON COMP 65	PROPOXYPHENE COMP 65	14
DECADRON	DEXAMETHASONE	9
DIAMOX	ACETAZOLAMIDE	6
DICAL-D	DICALCIUM PHOSPHATE	9
DILANTIN	PHENYTOIN SODIUM	13
DIMETANE	BROMPHENIRAMINE	
Tabs	Tabs	7
Elixir	Bromphen-Expect	21
DIMETAPP	BROMOPHEN	
Extentabs	T.D. Tabs	7
Elixir	Brotapp Elixir	21
DIUPRES	CHLOROSERPINE	8
DIURIL	CHLOROTHIAZIDE	8
DONNAGEL	QUIAGEL	22
DONNAGEL P.G.	QUIAGEL P.G.	22
DONNATAL	HYOSOPHEN	11
DORIDEN	GLUTETHIMIDE	10
DRAMAMINE	DIMENHYDRINATE	9

"A Full Line of Generics"

Plaintiff's Exhibit 57

RUGBY LABORATORIES Inc.

CAPSULES AND TABLETS

RUGBY GENERIC BRAND	SIZE	NDC No. PREFIX 0536	NATIONAL BRAND
CORTISONE			**CORTONE**
25 mg. Tabs	100	3530-01	
(White)			
CYCLANDELATE			**CYCLO-SPASMOL**
200 mg. Caps	100	3531-01	
(Blue)	1000	3531-10	
400 mg. Caps	100	3529-01	
(Blue/Red)	500	3529-05	
CYTOMINE			**CYTOMEL**
25 mcg. Tabs	100	3533-01	
(White)	1000	3533-10	
50 mcg. Tabs	100	3535-01	
(White)	1000	3535-10	
DEXAMETHASONE			**DECADRON**
0.75 mg. Tabs (Green)	100	3583-01	
1.5 mg. Tabs (Pink)	100	3584-01	
DICAL-CAPTAB			**DICAL D**
(Capsule Shaped Tab)	1000	3706-10	
DICALCIUM PHOSPHATE			
7½ gr. Tabs	1000	3704-10	
Caps	1000	3708-10	
Each capsule contains: dical phosph 4½ gr. vit. d 330 un cal. gluc 3 grs.			
DICYCLOMINE (See BENTOMINE)			**BENTYL**

NEW

DOXYCYCLINE HYCLATE

(Compare to Vibramycin)

100 mg. Caps (blue)

Available in

50's 0536-0230-06

CAPSULES AND TABLETS

RUGBY GENERIC BRAND	SIZE	NDC No. PREFIX 0536	NATIONAL BRAND
DIETHYLPROPION HCl ℭ			
75 mg. T.D. Tabs	100	3701-01	**TENUATE DOSPAN**
(White)	1000	3701-10	
DIGITALIS			
1½ gr. Tabs c.t.	1000	3720-10	
(Green)			
DIGITOXIN			**CRYSTO-DIGIN**
0.1 mg. Tabs (White)	1000	3730-10	
	5000	3730-50	
0.1 mg. Tabs (Pink)	1000	3726-10	
	5000	3726-50	
0.2 mg. Tabs (White)	1000	3732-10	
	5000	3732-50	
0.2 mg. Tabs (Pink)	1000	3736-10	
	5000	3736-50	
DIGOXIN			**LANOXIN**
0.25 mg. Tabs (White)	1000	3740-10	
	5000	3740-50	
DIMENHYDRINATE			**DRAMAMINE**
50 mg. Tabs (Yellow)	100	3742-01	
	1000	3742-10	
DIOCTYL SODIUM SULFOSUCCINATE			
100 mg. Tabs (Yellow)	1000	3750-10	
100 mg. Caps	1000	3752-10	
(Pink-Clear)			
100 mg. Soft Gel.	100	3756-01	**COLACE**
Caps (Red)	1000	3756-10	
250 mg. Caps	1000	3754-10	
(Red-Yellow)			
DSS-CASANTHRANOL			**PERI-COLACE**
Soft Gel. Caps	100	3751-01	
(Maroon)	1000	3751-10	
Tabs (Yellow)	1000	3753-10	
DIPHENATOL ℭ			**LOMOTIL**
Tabs (White)	100	3763-01	
	500	3763-05	

AMOXICILLIN

(Compare To Larotid)

Two Strengths Available

250 mg. Caps (Beige & Brown) — 500 mg. Caps (Beige)

20 Nassau Ave. Rockville Centre, N.Y. 11570

PLAINTIFF'S EXHIBIT 58

Fall 1979

Darby

DARBY DRUG CO. INC. 100 BANKS AVE., ROCKVILLE CENTRE, N.Y. 11571

NEW

AMPICILLIN TRIHYDRATE

F.D.A. CERTIFIED

Maroon/Gray

250 mg. Caps

310-0010 100— 4.70

310-0015 500— 21.95

310-0013 1M — 43.50

500 mg. Caps

310-0016 100— 9.40

310-0018 500— 44.35

310-0018 2x500— 87.90

TOLBUTAMIDE

0.5 gm. Tabs

(Similar to Orinase)

004-6880 100— 3.55

004-6882 500— 15.95

004-6885 1M — 29.95

VITAMIN B-12

(Crystalline) 1000 mcg./cc

	10	50
300-2040 10cc Vials	4.95	23.50
300-2060 30cc Vials	6.20	29.30

TETRACYCLINE HCl

F.D.A. CERTIFIED U.S.P.

250 mg. Orange & Yellow Caps

310-1820 100— 1.80

310-1825 1M — 14.65

310-1825 5x1M — 72.50

500 mg. Black & Yellow Caps

310-1870 100— 3.25

310-1875 1M — 27.90

TRI-HYDROSERPINE

Tabs

(Similar to Ser-ap-es)

004-7212 1000— 17.95

DIPYRIDAMOLE

(Similar to Persantine)

25 mg. Round Orange Tabs

003-7430 100— 4.75

003-7432 1M — 44.50

HYDRO-CHLOROTHIAZIDE

(Similar to Hydrodiuril)

50 mg. Tabs

003-9190 100— 1.00

003-9192 1M — 4.50

003-9195 1x5M — 20.95

AVAILABLE NEW '79-80 INFLUENZA VACCINE

(For 13 yrs. old & up)

TRIVALENT

Each 0.5cc Contains:

A/Brazil/78 ..... 7 mcg.

A/Texas/1/77 ..... 7 mcg.

B/Hong Kong ..... 7 mcg.

254-3752

5cc Vials

1—10.95 10—106.95

PLAINTIFF'S EXHIBIT 57

STERILE DISPOSABLE SYRINGES

© 1979 by DARBY DRUG CO., INC., 100 Banks Avenue, Rockville Centre, L.I., N.Y. 11571.
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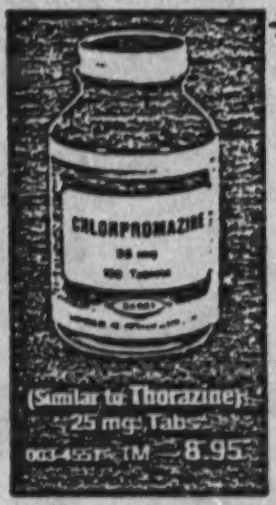
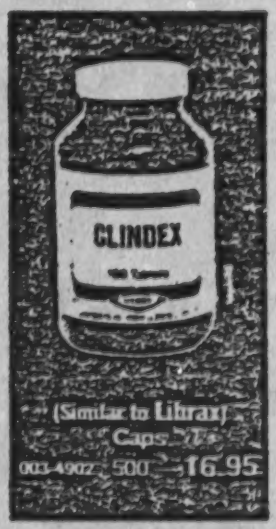
Plaintiff's Exhibit 58

Tablets/Capsules





NEW LOW PRICE

					1M	5x1M
CLINDEX (Similar to Librax) Caps (Green) .... 003-4900 100—3.75 003-4902 500—16.95	Chlordiazepoxide HCl 5 mg.	Clindinium Bromide 2.5 mg.		003-4928	32.50	
COLCHICINE Tabs 0.6 mg. (1/100 gr.) (White)				003-5040	7.95	39.50
Cold Tabs #1 (Red)	Chlorpheniramine Maleate 2 mg.	Phenacetin	162.5 mg.	003-4992	8.75	42.50
	Phenylephrine HCl 4 mg.	Caffeine	32.4 mg.	Salicylamide		227.5 mg.
Cold Tabs #2 (Purple)	Phenylpropanolamine HCl 25 mg.	Tartan Hydrate	2½ gr.	003-5000	10.25	49.75
	Chlorpheniramine Maleate 2 mg.	Acetaminophen	5 gr.			
	Pyrilamine Maleate 10 mg.					
Cold Tabs #2 with DMH (Rose)	Phenylpropanolamine HCl 25 mg.	Tartan Hydrate	162 mg.	003-5010	15.50	75.25
	Chlorpheniramine Maleate 2.5 mg.	Acetaminophen	325 mg.			
	Pyrilamine Maleate 10 mg.	Dextromethorphan H Br	7½ mg.			
Cold Capsules—Mild (Yellow/Blue)	Aspirin 227 mg.	Pyrilamine Maleate	10 mg.	003-5040	9.55	45.35
	Phenacetin 162 mg.	Caffeine	32.5 mg.			
Cold Capsules—Medium (Yellow/Purple)	Aspirin 162 mg.	Caffeine	32.4 mg.	003-5060	11.50	56.50
	Phenacetin 162 mg.	Pyrilamine Maleate	25 mg.			
Cold Capsules—Forte (Brown/White)	Aspirin 2½ gr.	Camphor	⅛ gr.	003-5080	10.90	53.20
	Phenacetin 1½ gr.	Pseudephrine	1/60 gr.	Atropine Sulfate	1/1000 gr.	
	Quinine Sulfate ¼ gr.	Aloin	1/10 gr.			
Conjugated Estrogens U.S.P. 0.625 mg. Tabs (Maroon)		003-5160 100— 4.50		003-5161	35.25	
1.25 mg. Tabs (Yellow)		003-5220 100— 3.40		003-5221	48.95	
2.50 mg. Tabs (Purple)		003-5290 100—10.65		003-5295	88.75	
Cortisone Tablets 25 mg. (White) .... 003-5300 100—3.95		003-5302 500—18.50		003-5302	36.70	
Cough Wafers Mentholated	Benzocaine ⅛ gr. — Licorice P.S. 1/16 gr.	Oil of Anise, Eucalyptol and Menthol		003-5340	4.20	20.20
CYCLANDELATE (Similar to Cyclospasmol) 200 mg. Caps (Blue)		003-5310 100— 1.95		003-5315	15.45	
400 mg. Caps ..... 003-5290 100—3.65		003-5292 500—14.75				
CYPROHEPTADINE HCl (Similar to Periactin) 4 mg. Tabs (White) 003-5150 100—4.35		003-5156 500—19.25				

ONE OF AMERICA'S MOST POPULAR GENERIC FORMULAS

DARLITE®
Capsule Shaped Tabs (S.C. Brown) ..... 003-5541 — 1M 7.95 — 5x1M 38.75

D	400 I.U.	Niacinamide	10 mg.	Inositol	5 mg.
A	5,000 I.U.	Pot. Sulfate	5 mg.	Phosphorus	60 mg.
C	60 mg.	Zinc Sulfate	0.2 mg.	Ferrous Sulf.	15 mg.
B1	5.0 mg.	Dried Yeast	10 mg.	Iodine (Pot. Iodide)	0.12 mg.
B2	3.4 mg.	Wheat Germ Oil	10 mg.	Copper Sulfate	0.25 mg.
B6	0.6 mg.	Biotin	3 mcg.	Manganese Sulf.	0.25 mg.
B12	1.5 mcg.	Choline Bitar.	5 mg.	Magnesium Sulf.	5 mg.
E	3 I.U.	Dical. Phos.	110 mg.	Para-Amino-Benzoic Acid	5 mg.
Cal. Pan.	3.3 mg.				

Also Available ..... 003-5540 100—1.05 10x100—9.90

DANTHRON (Similar to Modane)
75 mg. S.C. Tab (Yellow) ..... 003-5560 100—1.40 003-5565 10.95

DECONGEST (Similar to Dristan)
Tabs (White) ..... 003-5710 100—1.15 003-5710 10.75
Phenylephrine HCl 5 mg. — Phenindamine Tartrate 10 mg. — Aspirin, Caffeine — Aluminum Hydroxide — Magnesium Carbonate Co-dried gel.

Plaintiff's Exhibit 58

C-D

NAME BRAND

BRANDED GENERICS by DARBY

ORDER BY NUMBER PLEASE

GENERIC GUIDE

ection

DARBY

CYCLOSPASMOL
200 MG. CAPS
Ives
144-5200 100— 8.85

CYCLANDELATE
200 MG. CAPS
Darby
003-5310 100— 1.95
003-5316 1M—15.45

® DARVON
65 MG. PULVULES
(Propoxyphene HCl)
Lilly
188-5400 100— 8.40
188-5405 500—38.95

PROPOXYPHENE HCl ®
65 MG. CAPSULES
Darby
004-3820 100—1.95
004-3822 500—7.50

® DARVON
COMP-65
Lilly

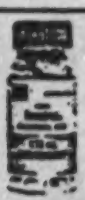
Propoxyphene HCl	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg.

188-5500 100— 8.75
188-5505 500—40.75

PROPOXYPHENE ®
COMP-65
Darby

Propoxyphene HCl	65 mg.
Aspirin	227 mg.
Phenacetin	162 mg.
Caffeine	32.4 mg.

004-3830 100— 2.50
004-3832 500— 9.95
004-3834 1M—18.95



DECADRON
0.75 MG. TABS
(Dexamethasone)
Merck
172-5500 100—15.35

DEXAMETHASONE
0.75 MG. TABS
Darby
003-5320 100— 3.90
003-5330 10x100—36.50

DECHOLIN TABS
(Dehydrocholic Acid 250 mg.)
Dome
133-3030 100— 7.50
133-3033 500—37.50

DEHYDROCHOLIC
ACID
250 MG. TABS
Darby
003-5700 1M—28.95

DELTASONE
5 MG. TABS
(Prednisone)
Upjohn
228-2100 100—2.05

PREDNISONE
5 MG. TABS
Darby
004-3842 1M—8.50

Plaintiff's Exhibit 58

IMPORTANT! Please add Stock No. when ordering

C

		Size	Price
	CRYSTODIGIN		
188-2150	0.05 mg.	500—	3.25
188-2156	0.1 mg. (5M—40.40)	500—	5.25
173-1580	Cuprimine 125 mg. caps	100—	15.40
173-1306	Cuprimine 250 mg. caps	100—	21.95
264-3460	Cuticura Soap Bath Bars	3—	1.65
104-2530	Cyclogyl 0.5%	15ml—	6.30
104-2600	Cyclogyl 1.0%	15ml—	7.35
104-2620	Cyclogyl 2.0%	5ml—	4.00
	CYCLOSPASMOL (Cyclandelate)		
144-0100	100 mg. tabs. (500—20.75)	100—	4.40
144-0200	200 mg. caps. (500—41.50)	100—	8.85
144-0396	400 mg. caps	100—	15.95
158-2300	Cytellin	1pt.—	6.95
230-2000	Cytomel 5 mcg.	100—	2.00
230-2100	Cytomel 25 mcg. (1M—28.75)	100—	3.00
230-2116	Cytomel 50 mcg.	100—	4.55
168-0725	Cytoxan 25 mg tabs.	100—	16.45
168-0750	Cytoxan 50 mg. tabs	100—	30.25

D

			Size	Price
208-1500	D.H.E. 45 1cc amps		20—	18.45
218-0400	Dacriose Sol		4oz—	2.30
174-1170	Dactil w/Pheno tabs		50—	3.65
234-0260	Dainite-KI tabs		100—	13.05
220-0710	Daimane 15 mg. caps.	CIV	100—	9.20
220-0715		CIV	500—	44.90
220-0730	Daimane 30 mg. caps.	CIV	100—	10.95
220-0735		CIV	500—	53.95
106-0310	Danex Shampoo		4oz—	2.25
248-0800	Danocrine 200 mg caps		100—	97.50
136-0972	Dantrium 25 mg. caps.		100—	15.10
136-0982	Dantrium 100 mg. caps		100—	20.35
136-0990	Dantrium O.S. 5mg./ml. 118 ml.		1—	4.40
165-1010	Dara Shampoo		1pt.—	3.30
175-1700	Daranide 50 mg. tabs		100—	10.35
220-2300	Darbid 5 mg. tabs (Isopropamide)		50—	4.30
168-0360	Daricon 10 mg. tabs. (500—65.75)		60—	7.90
168-0370	Daricon-PB tabs.		100—	11.40
186-2340	Darvocet-N 50 tabs.	CIV	100—	6.15
186-2346		CIV	500—	28.35
186-2347	Darvocet-N 100 tabs.	CIV	100—	11.35
186-2348		CIV	500—	53.15
186-2360	Darvon 32 mg.	CIV	100—	4.75
186-2365		CIV	500—	21.95
186-2460	Darvon Comp-32.	CIV	100—	5.15
186-2465		CIV	500—	24.70
186-2400	Darvon 65 mg.	CIV	100—	8.40
186-2405		CIV	500—	38.95
186-2500	Darvon Comp-65.	CIV	100—	8.75
186-2505		CIV	500—	40.75
186-2210	Darvon-N tabs.	CIV	100—	10.25
186-2329	Darvon-N Susp. 50 mg/5cc.	CIV	1pt—	5.40
186-2325	Darvon-N w/A.S.A.	CIV	100—	10.40
186-2330		CIV	500—	48.85
113-0500	Datril tabs.		100—	1.70
113-0510	Datril 500 X-Strength caps		72—	1.50

Compare DARBY'S Low, Low Prices For Big Savings!!

©©© D.E.A. No. Required

D (Continued)

		Size	Price
139-1960	Daxolin caps 10 mg.	100—	12.65
139-1950	Daxolin caps 25 mg.	100—	18.95
139-1970	Daxolin caps 50 mg.	100—	25.50
196-0200	Deaner 100 mg. tabs.	50—	10.10
196-0230	Deaner-250	50—	15.40
160-0425	Debrox Drops	15cc—	1.65
191-0800	Debrisan Pwd. 7x4 gm. Pk	1—	16.80
191-0805	Debrisan Pwd. 14x4 gm. Pk.	1—	32.40
191-0810	Debrisan 60 gm. Pwd	1—	32.40
191-0815	Debrisan 120 gm. Pwd	1—	62.40
	DECADRON (Dexamethasone)		
173-1900	4 mg./cc. (25cc—26.65)	5cc—	5.50
173-2300	4 mg./cc w/Xylocaine	5cc—	5.95
173-2110	L.A. Suspension	5cc—	7.35
173-1960	0.5 mg. tabs	100—	12.30
173-2000	0.75 mg. tabs	100—	15.35
173-1930	4 mg. tabs	50—	22.35
173-2100	Elixir 100cc	1—	4.00
173-2125	Ophth. Oint. 0.05% 3.5 gm.	1—	1.50
173-2150	Ophth. Sol. 0.1% 2.5cc	1—	2.10
173-2155	Ophth. Sol. 0.1%	5cc—	3.65
173-2175	Respihaler Aerosol	1—	6.75
173-2200	Turbinaire 12.6 gm.	1—	7.15
173-2210	Turbinaire Refill 12.6 gm.	1—	6.35
173-2250	Topical Cream 0.1%	15gm—	2.80
184-0800	Deca-Durabolin Box 4 x 1cc (50 mg.)	1—	19.20
184-0900	Deca-Durabolin 50 mg./cc	2cc—	8.75
184-0910	Deca-Durabolin 100 mg./cc	2cc—	16.20
173-3480	Decaspray Topical Aerosol	25gm—	3.60
139-2030	Decholin tabs. (500—37.50)	100—	7.60
	DECLOMYCIN		
154-4800	150 mg. caps. (100—40.60)	16—	6.75
154-4810	150 mg. tabs. (100—40.35)	16—	6.75
154-4830	300 mg. tabs. (48—35.50)	12—	9.10
154-4820	Declomycin Syrup	2oz—	2.80
154-5000	Declostatin caps. (100—46.80)	16—	7.75
135-0300	Deconamine SR caps.	100—	11.95
117-0200	Degest-2	15cc—	1.95
223-0450	Delaclumone. (10—54.75)	5cc—	5.85
	Delalutin		
223-0600	125 mg./cc. (10—106.25)	10cc—	11.35
223-0800	250 mg./cc. (10—95.70)	5cc—	10.25
223-0700	Delestestryl 200mg./cc. (10—88.80)	5cc—	9.35
174-1200	Delcid Antacid	8oz—	2.10
	Delestrogen		
222-0600	10 mg./cc. (10—51.70)	5cc—	5.50
222-0900	20 mg./cc. (10—72.30)	5cc—	7.70
222-1000	40 mg./cc. (10—119.95)	5cc—	12.70
182-0300	Delfen Cream tube	1—	3.50
182-0400	Delfen Cream w/Applicator	1—	4.10
182-0500	Delfen Vag. Foam 20 gm. w/App.	1—	3.80
182-0550	Delfen Vaginal Foam Refill 20 gm.	1—	3.50
182-0496	Delfen Vag. Foam 50 gm	1—	4.70
228-2100	Deltasone 5 mg. tabs	100—	2.05
214-1900	Demazin repetabs	100—	8.20
243-1030	Demerol 50 mg. tabs. CII	100—	10.35
243-1050	Demerol 50 mg./cc. CII	30cc—	4.35
		10x30cc—	41.35

DEXAMETHASONE
(Similar to Decadron)
4 mg./cc
201-4150
5 cc—1.15 10x5 cc—10.90

(C)—SEE PAGE 35 BEFORE ORDERING CLASS II ITEMS

PLAINTIFF'S EXHIBIT 59

Sherry Tablets/Capsules

CHLOROSERP-250
(Comparable to Diuprex-250)

Tabs	003-4630	100	2.75
Each tab contains: Reserpine 0.125 mg., Chlorothiazide 250 mg.	003-4635	1M	23.75

CHLOROTHIAZIDE
(Comparable to Diuril)

250 mg. White Tabs	003-4600	100	2.40
	003-4605	1M	21.30
	003-4610	100	3.55
500 mg. White Tabs	003-4615	1M	34.50

CHLORPHENIRAMINE MALEATE
(Comparable to Chlortrimeton, Teldrin)

[illegible] mg. Yellow Tabs	003-4650	1M	1.35
	003-4661	5x1M	6.20
[illegible] S.C. Yellow T.D. Tabs	003-4720	1M	4.30
	003-4720	5x1M	20.40
[illegible] T.D. Tabs	003-4780	1M	4.50
	003-4780	5x1M	22.50
8 mg. Green/Clear T.D. Caps	003-4760	1M	7.50
	003-4760	5x1M	38.40
12 mg. Green-Clear T.D. Caps	003-4820	1M	8.35
	003-4820	5x1M	40.50

CHLORPHENIRAMINE W/SPC

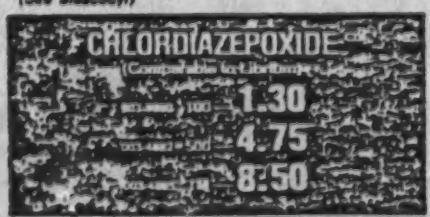
Tabs	003-4840	1M	3.85
Each maroon tab contains: Caffeine 3½ gr., Acetophenetidin 2½ gr., Salicylamide 3½ gr.	003-4840	5x1M	18.75

CHLORPHENTERMINE HCl
(See Teramine)

CHLORPROMAZINE
(Comparable to Thorazine)

10 mg. S.C. Rust Tabs	003-4545	100	1.00
	003-4547	1M	8.85
[illegible] S.C. Rust Tabs	003-4550	100	1.30
	003-4551	1M	9.15
[illegible] S.C. Rust Tabs	003-4560	100	1.85
	003-4561	1M	12.85
100 mg. S.C. Rust Tabs	003-4570	100	2.55
	003-4572	1M	22.50

CODYLAX E.C.
(See Bisacodyl)



COLCHICINE

Tabs 0.6 mg. (1/100 gr.)	003-4940	1M	7.30
	003-4940	5x1M	36.25

COLDAID
(See Allerprop)

CONJUGATED ESTROGENS
(Comparable to Premarin)

0.625 mg. S.C. Maroon Tabs	003-5160	100	2.40
	003-5161	1M	19.50
1.25 mg. S.C. Yellow Tabs	003-5220	100	3.40
	003-5221	1M	30.85
2.5 mg. S.C. Purple Tabs	003-5280	100	5.45
	003-5285	1M	51.95

CORTISONE ACETATE
(Comparable to Cortone Acetate)

White Tabs 25 mg.	003-5300	100	3.80
	003-5302	500	17.60

COUGH DISCS

Each disc contains: Anise, Benzocaine 8 mg., Eucalyptol q.s., Menthol, P.E. Licorice 1/16 gr.	003-5340	1M	2.75
	003-5340	5x1M	12.95

CYCLANDELATE
(Comparable to Cyclospasmol)

200 mg. Blue Caps	003-5310	100	1.00
	003-5315	1M	12.40
400 mg. Red/Blue Caps	003-5290	100	3.85
	003-5293	500	17.20

CYTOMINE
(Comparable to Cytomel)

25 mcg. White Tabs	003-5330	100	1.00
	003-5335	1M	8.50
50 mcg. White Tabs	003-5355	100	1.15
	003-5357	1M	8.20

d...

DEHYDROCHOLIC ACID
(Comparable to Cytomel)

3¼ gr. White Tabs	003-5760	1M	22.50

DEXAMETHASONE
(Comparable to Decadron)

Tabs 0.75 mg.	003-5830	100	3.95
	003-5830	10x100	34.50

DICYCLOMINE HCl N.F.
(Comparable to Bentyl)

10 mg. Blue Caps	003-3670	100	1.00
	003-3675	1M	8.85
10 mg. w/Pb. 15 mg. blue/Clear Caps	003-3680	100	1.25
	003-3685	1M	8.30
20 mg. Blue Tabs	003-3770	100	1.00
	003-3775	1M	8.85
20 mg. w/Pb. 15 mg. White Tabs	003-3780	100	1.15
	003-3785	1M	7.50

PLAINTIFF'S EXHIBIT 60

MD Pharmaceutical Inc.
Generic Drug Manufacturer
3501 West Garry Avenue
Santa Ana, California 92704
(714) 556-3941

Product List

BRAND NAME	GENERIC NAME
ACTIFED	TRIPROLIDINE - PSEUDOEPHEDRINE
CYCLOSPASMOL	CYCLANDELATE 200 MG.
DORIDEN	GLUTETHIMIDE 0.5 MG.
LOMOTIL	DIPHENOXYLATE - ATROPINE
ELAVIL	AMITRIPTYLINE 10 MG AMITRIPTYLINE 25 MG AMITRIPTYLINE 50 MG
RITALIN	METHYLPHENIDATE 5 MG METHYLPHENIDATE 10 MG METHYLPHENIDATE 20 MG

NOTE:

PLAINTIFF'S EXHIBIT 64

HHR 4X9624

T I I I 5 5 7-0 3-1

PHYSICIAN SCREENING QUESTIONNAIRE

Physician Name: _____

Address: _____

City/State: _____

Telephone Number: _____ _____
(AREA CODE)

Date of call to Physician: _____

Hello. I am _____ of Heller Research, a marketing research firm that is presently doing a study in the pharmaceutical field.

A. We hope that you will be willing to cooperate with us in our research, and would appreciate your giving us about 5 to 10 minutes of your time for a personal interview. We will be pleased to pay you your normal fee for an office visit.

B. Can we count on your participation in this important research?

YES ( ) 9-1

NO ( ) ⟶TERMINATE

C. Date of appointment with physician: _____

Name of Interviewer Placing Call: _____

NOTE: If the physician inquires about the nature of the research, state that it involves questions about drugs that physicians prescribe. Do not volunteer any other information. Do assure him that you are NOT selling anything.

Plaintiff's Exhibit 64

MHR #X96Z4

PHYSICIAN QUESTIONNAIRE

DOCTOR'S NAME: _____ TELEPHONE CONTACT DATE: _____

ADDRESS: _____ APPOINTMENT DATE: _____

_____

TELEPHONE NUMBER: _____

Hello Dr. _____, I am _____, a representative from Heller Research Corp., a firm that does surveys in the pharmaceutical field. I would appreciate your assistance for no more than 10 or 15 minutes. To show our appreciation, I have a gift for you as a token of appreciation for your help.

1. What do you consider to be your medical specialty? (e.g., general practitioner, internist, cardiologist, etc.)

_____ 10-11-

2. Approximately what percent of your patients are over sixty-five?

_____ % 12-13-

3. I would like to talk to you about medicati[illegible] that can be prescribed for some elderly people.

(POUR THE CAPSULES ON THE DESK OR TABLE BETWEEN YOU AND THE DOCTOR)

4. Do you recognize any of these capsules?

YES ( )14-1

NO ( ) -2 → SKIP TO Q.8

5. Would you separate the capsules you do recognize? (RECORD WHICH CAPSULES THE DOCTOR SEPARATES)

All Blue	( )15-1	
Brown/White	( )	-2
Blue/Red	( )	-3
Maroon/White	( )	-4

6. How did you recognize the capsules you separated?

_____ 16-

_____ 17-

_____ 18-

_____ 19-

7. Can you tell me the name of each product you separated? To help me in recording this, please point to the product as you identify it, or tell me the color of the product as you identify it?

All Blue _____ 20- Blue/Red _____ 22-

Brown/White _____ 21- Maroon/White _____ 23-

(1)

Plaintiff's Exhibit 64

(QUESTIONS 8 AND 9 ARE TO BE ASKED ONLY IN THE FOLLOWING CIRCUMSTANCES:)

(A) IF THE ANSWER TO Q.4 IS "NO"

(B) IF ALL BLUE OR BLUE/RED ARE NOT AMONG THE CAPSULES SEPARATED IN RESPONSE TO Q.5

(C) IF CYCLOSPASMOL IS NOT LISTED IN RESPONSE TO Q.7

(HAND CARD A TO PHYSICIAN) (INTERVIEWER: PLEASE INDICATE IN THE SPACE PROVIDED, THE NUMBER NEXT TO THE DRUG CYCLOSPASMOL THAT APPEARS ON THE CARD SHOWN RESPONDENT _____.)

8. I am going to show you a list of names of some drug products. Do you now recognize any of the capsules?

YES ( )24-1 ⟶ ASK Q.9

NO ( ) -2 ⟶ SKIP TO Q.10

9. Tell me by name which of the capsules you now recognize. To help me in recording them, please point to the particular capsule as you identify it, or tell me the color of the product as you identify it.

All Blue ( )25-1

Blue/Red ( ) -2

10. On this interview we are going to talk about Cyclospasmol. Have you ever prescribed Cyclospasmol?

YES ( )26-1 ⟶ ASK Q.11
NO ( ) -2 ⟶ SKIP TO LAST PAGE

11. When was the last time you prescribed Cyclospasmol?

Less than 1 month ago	)27-1
1-3 months ago	-2
Between 3 & 6 months ago	-3
More than 6 months ago	-4

Plaintiff's Exhibit 64

12. What dosage of Cyclospasmol have you prescribed -- the 200 mg. or the 400 mg.?

200 mg.	( )	28-1
400 mg.	( )	-2
Both	( )	-3

13. We are interested in determining how patients who take Cyclospasmol identify the product. I would appreciate your determining whether any of your patients would like to participate in the survey. We will not be asking them any questions about their health. We're merely interested in learning whether they can recognize certain capsules we'll be showing them. I'm sure they will find it very interesting and diverting. We will need only a few minutes of their time and will pay them for their time.

Of course, we will compensate you or your nurse or secretary for the time required to telephone the patients. If your secretary could take the time out now while I wait, I could pay her $10 for the name of each patient she finds willing to cooperate in the survey.

When the patient is called, please do not tell the patient anything about the kind of survey we're doing, except to say that it is in the pharmaceutical area. In order to make sure that their answers are spontaneous, they should not be told the kinds of questions they may be asked. Also, the names of specific drug products should not be mentioned. Of course, I'm sure the nurse or secretary will want to assure the patient that asking them whether they wish to participate does not mean there is anything wrong, and that participation is voluntary on their part.

Please let me know in each instance which dosage of Cyclospasmol you have prescribed for each patient who is willing to be interviewed. I would appreciate having the names of only those patients who you believe can respond intelligently to survey questions, that is, they are still ambulatory, alert and fairly self-sufficient.

(NOTE: IF A PHYSICIAN CANNOT SUPPLY YOU WITH THE NAMES AND DOSAGE FORMS PRESCRIBED FOR EACH PATIENT AT THE TIME OF THE INTERVIEW, PLEASE ARRANGE TO TELEPHONE HIS OFFICE FOR THE LIST AT A GIVEN TIME EITHER LATER IN THE SAME DAY OR ON THE NEXT DAY. INDICATE ON THE QUESTIONNAIRE THAT THE INFORMATION AS TO NAME AND DOSAGE WAS NOT OBTAINED DURING THE INTERVIEW, BUT BY TELEPHONE AFTERWARDS AND RECORD (1) THE DATE WHEN THE NAMES AND DOSAGES WERE OBTAINED AND (2) THE IDENTITY OF THE PERSONS WHO GAVE THE INFORMATION TO YOU BY TELEPHONE)

14. Patient Names, Addresses, Telephone Numbers — Dosage Prescribed:

_____	200mg. ( )29-	400mg. ( )33-
_____		
_____	200mg. ( )30-	400mg. ( )34-
_____		
_____	200mg. ( )31-	400mg. ( )35-
_____		
_____	200mg. ( )32-	400mg. ( )36-
_____		

Plaintiff's Exhibit 64

Thank you for your help. (GIVE DOCTOR AND NURSE FEES)

Interviewer name: _____

Interview Date: _____

IF NECESSARY:

DATE OF CALLBACK FOR PATIENT NAMES: _____

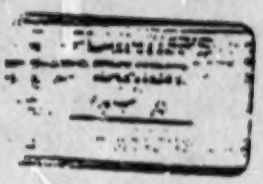
NAME OF PERSON GIVING PATIENT NAMES: _____

$_____ GIVEN TO NURSE/SECRETARY

$_____ GIVEN TO DOCTOR

(4)

Plaintiff's Exhibit 64



CARD A

1. CYCLOSPASMOL
2. PAVABID
3. DYAZIDE
4. SERAX
5. MONISTAT - 7
6. PROLOID
7. NALDECON
8. LIDEX
9. ANUSOL HC
10. MELLARIL

Plaintiff's Exhibit 64

CARD A

1. MELLARIL
2. CYCLOSPASMOL
3. PAVABID
4. DYAZIDE
5. SERAX
6. MONISTAT - 7
7. PROLOID
8. NALDECON
9. LIDEX
10. ANUSOL HC

Plaintiff's Exhibit 64

CARD A

1. ANUSOL HC
2. MELLARIL
3. CYCLOSPASMOL
4. PAVABID
5. DYAZIDE
6. SERAX
7. MONISTAT - 7
8. PROLOID
9. NALDECON
10. LIDEX

Plaintiff's Exhibit 64

CARD A

1. LIDEX
2. ANUSOL HC
3. MELLARIL
4. CYCLOSPASMOL
5. PAVABID
6. DYAZIDE
7. SERAX
8. MONISTAT - 7
9. PROLOID
10. NALDECON

Plaintiff's Exhibit 64

CARD A

1. NALDECON
2. LIDEX
3. ANUSOL HC
4. MELLARIL
5. CYCLOSPASMOL
6. PAVABID
7. DYAZIDE
8. SERAX
9. MONISTAT - 7
10. PROLOID

Plaintiff's Exhibit 64

CARD A

1. PROLOID
2. NALDECON
3. LIDEX
4. ANUSOL HC
5. MELLARIL
6. CYCLOSPASMOL
7. PAVABID
8. DYAZIDE
9. SERAX
10. MONISTAT - 7

Plaintiff's Exhibit 64

CARD A

1. MONISTAT - 7
2. PROLOID
3. NALDECON
4. LIDEX
5. ANUSOL HC
6. MELLARIL
7. CYCLOSPASMOL
8. PAVABID
9. DYAZIDE
10. SERAX

Plaintiff's Exhibit 64

CARD A

1. SERAX
2. MONISTAT - 7
3. PROLOID
4. NALDECON
5. LIDEX
6. ANUSOL HC
7. MELLARIL
8. CYCLOSPASMOL
9. PAVABID
10. DYAZIDE

Plaintiff's Exhibit 64

CARD A

1. DYAZIDE
2. SERAX
3. MONISTAT - 7
4. PROLOID
5. NALDECON
6. LIDEX
7. ANUSOL HC
8. MELLARIL
9. CYCLOSPASMOL
10. PAVABID

Plaintiff's Exhibit 64

CARD A

1. RAVABID
2. DYAZIDE
3. SERAX
4. MONISTAT - 7
5. PROLOID
6. NALDECON
7. LIDEX
8. ANUSOL HC
9. MELLARIL
10. CYCLOSPASMOL

PLAINTIFF'S EXHIBIT 65

HHR #X9624

T 2 3 4 5 6 7-0
9-2

PATIENT QUESTIONNAIRE

NAME OF PATIENT: _____ DOCTOR REFERRAL: _____

ADDRESS: _____ APPOINTMENT DATE: _____

_____

TELEPHONE #: _____ RECALL DATE: _____

MALE ( )9-1 FEMALE ( ) -2 CYCLOSPASMOL DOSAGE INDICATED BY DOCTOR: → 200 mg. ( )10-1 400 mg. ( ) -2

Hello, I am _____. I called you earlier about a survey we are conducting. I am with _____. This is my identification card. I will need only a few minutes of your time. In exchange for your help, we are offering you $10.00 which I will leave with you.

1. Did your doctor or his nurse call you about this interview? YES ( ) 11-1 NO ( ) -2 → SKIP TO INSTRUCTION BEFORE Q.2

What did he tell you? _____ 13-

_____ 14-

_____ 15-

_____ 16-

(REMOVE THE 3 PRESCRIPTION BOTTLES FROM YOUR BAG AND PLACE THEM ON A TABLE IN FRONT OF THE RESPONDENT. INDICATE BELOW WHETHER THE BOTTLES YOU ARE USING CONTAIN THE 200 mg. OR THE 400 mg. DOSAGE OF THE CAPSULES:)

200 mg ( )16-1 400 mg ( ) -2

2. Please remove the cap from each bottle and place the cap next to the bottle. (WAIT UNTIL RESPONDENT DOES THIS).

3. Do you recognize the capsules in each of these bottles?

YES ( )17-1
NO ( ) -2 → SKIP TO Q.6

Other Response: _____

4. How do you recognize them: _____ 18-

_____ 19-

_____ 20-

_____ 21-

5. What is the name of the medication: Name: _____ 22-

Don't Know ----------( ) -y

Plaintiff's Exhibit 65

(Q.6 & 7 ARE TO BE ASKED ONLY OF THE PATIENTS WHO DID NOT RECOGNIZE THE CAPSULES IN RESPONSE TO Q.3 OR DID NOT FURNISH THE NAME CYCLOSPASMOL IN RESPONSE TO Q.5)

(HAND RESPONDENT CARD B) (INTERVIEWER: PLEASE INDICATE IN THE SPACE PROVIDED, THE NUMBER NEXT TO THE DRUG CYCLOSPASMOL THAT APPEARS ON THE CARD SHOWN RESPONDENT _____)

6. Do you think the capsules are any of the drugs that are on this list? Do not guess if you do not know.

YES ( )23-1→ASK Q.7
NO ( ) -2 } SKIP TO Q.8a
DON'T KNOW ( ) -3 }

7. Please tell me which drug you think the capsules are?

_____ 24-

8a. Has your doctor ever prescribed CYCLOSPASMOL for you?

YES ( )25-1→SKIP TO INSTRUCTION BEFORE Q.9
NO ( ) -2 } ASK Q.8b
DON'T KNOW ( ) -3 }

8b. (IF THE ANSWER IS NO OR DON'T KNOW - THEN ASK:) Has your doctor ever prescribed medication that looks like this for you?

YES ( )26-1
NO ( ) -2 } SKIP TO Q.15
DON'T KNOW ( ) -3 }

Plaintiff's Exhibit 65

I would appreciate it if you would let me see the bottle of the medication your doctor prescribed for you that looks like the medication in the bottles shown to you. (HAVE THE RESPONDENT BRING HIS/HER MEDICATION TO THE TABLE)

9. Is the label on the bottle the same as when you received it from the druggist?

YES ( )27-1
NO ( ) -2

If not, please tell me how it has been changed? _____ 28-
29-
_____ 30-
_____ 31-

10. Are the capsules in the bottle the same ones that were in the bottle when you received it from the druggist?

YES ( )32-1
NO ( ) -2

If not, in what way are they different? _____ 33-
34-
_____ 35-
_____ 36-

11. (RECORD ALL DETAILS ON THE LABEL OF THE RESPONDENT'S BOTTLE)

Pharmacy Name & Address: _____
_____

Name of Patient: _____

Name of Doctor: _____

Date of Prescription: _____ Prescription No.: _____

(COPY HERE ALL OTHER INFORMATION TYPES OR HANDWRITTEN EXACTLY AS IT APPEARS ON THE LABEL:
_____ 37-
_____ 38-
_____ 39-
40-

12. (ASK THE RESPONDENT PERMISSION TO POUR THE CAPSULES ON A PLATE AND EXAMINE THEM. RECORD THE FOLLOWING INFORMATION:)

(a) Is there a name or names printed on the capsules? YES ( )41-1 NO ( ) -2

If so, what are the name or names? _____ 42-
_____ 43-

(b) Is there a number printed on the capsules? YES ( )44-1 NO ( ) -2

(c) What color are the capsules? _____ 45-
46-

(d) Do all of the capsules have the same appearance (e.g. do some have markings, and others none)? YES ( )47-1 NO ( ) -2

If not, what differences in appearance do you note? _____ 48-
49-
_____ 50-
_____ 51-

Plaintiff's Exhibit 65

13. How long have you been taking this medication?

_____ 52-
53-
_____ 54-
55-

14. How many capsules do you take every day? _____ 56-

15. How old are you? _____ 57-
58-

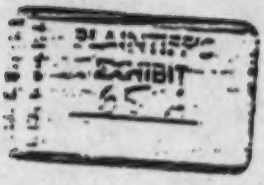
You have been very helpful in answering the questions. To express our appreciation, I would like to offer you $10.00.

Thank you and have a good day.

Interviewer's Name: _____

Date of Interview: _____

Plaintiff's Exhibit 65



CARD D

1. CYCLOSPASMOL
2. SERAX
3. MONISTAT - 7
4. PROLOID
5. NALDECON
6. LIDEX
7. ANUSOL HC
8. MELLARIL
9. TELDRIN
10. LOTRIMIN

Plaintiff's Exhibit 65

CARD B

1. LOTRIMIN
2. CYCLOSPASMOL
3. SERAX
4. MONISTAT - 7
5. PROLOID
6. NALDECON
7. LIDEX
8. ANUSOL HC
9. MELLARIL
10. TELDRIN

Plaintiff's Exhibit 65

CARD B

1. TELDRIN
2. LOTRIMIN
3. CYCLOSPASMOL
4. SERAX
5. MONISTAT - 7
6. PROLOID
7. NALDECON
8. LIDEX
9. ANUSOL HC
10. MELLARIL

Plaintiff's Exhibit 65

CARD B

1. MELLARIL
2. TELDRIN
3. LOTRIMIN
4. CYCLOSPASMOL
5. SERAX
6. MONISTAT - 7
7. PROLOID
8. NALDECON
9. LIDEX
10. ANUSOL HC

Plaintiff's Exhibit 65

CARD P

1. ANUSOL HC
2. MELLARIL
3. TELDRIN
4. LOTRIMIN
5. CYCLOSPASMOL
6. SERAX
7. MONISTAT - 7
8. PROLOID
9. NALDECON
10. LIDEX

Plaintiff's Exhibit 65

CARD B

1. LIDEX
2. ANUSOL HC
3. MELLARIL
4. TELDRIN
5. LOTRIMIN
6. CYCLOSPASMOL
7. SERAX
8. MONISTAT - 7
9. PROLOID
10. NALDECON

Plaintiff's Exhibit 65

CARD B

1. NALDECON
2. LIDEX
3. ANUSOL HC
4. MELLARIL
5. TELDRIN
6. LOTRIMIN
7. CYCLOSPASMOL
8. SERAX
9. MONISTAT - 7
10. PROLOID

Plaintiff's Exhibit 65

CARD B

1. PROLOID
2. NALDECON
3. LIDEX
4. ANUSOL HC
5. MELLARIL
6. TELDRIN
7. LOTRIMIN
8. CYCLOSPASMOL
9. SERAX
10. MONISTAT - 7

Plaintiff's Exhibit 65

CARD B

1. MONISTAT - 7
2. PROLOID
3. NALDECON
4. LIDEX
5. ANUSOL HC
6. MELLARIL
7. TELDRIN
8. LOTRIMIN
9. CYCLOSPASMOL
10. SERAX

Plaintiff's Exhibit 65

CARD B

1. SERAX
2. MONISTAT - 7
3. PROLOID
4. NALDECON
5. LIDEX
6. ANUSOL HC
7. MELLARIL
8. TELDRIN
9. LOTRIMIN
10. CYCLOSPASMOL

PLAINTIFF'S EXHIBIT 66

HRR #X9624

ADMINISTRATIVE INSTRUCTIONS

DOCTOR STUDY

Enclosed are the following materials for use on this study:

2 COPIES OF ADMINISTRATIVE INSTRUCTIONS

15 PHYSICIAN SCREENING QUESTIONNAIRES

15 PHYSICIAN QUESTIONNAIRES

15 PATIENT QUESTIONNAIRES

2 INTERVIEWING INSTRUCTIONS

6 VALIDATION SHEETS

1 UNLABELED PLASTIC BOTTLE

3 PLASTIC BOTTLES LABELED CYCLANDELATE 400 mg.

3 PLASTIC BOTTLES LABELED CYCLANDELATE 200 mg.

LISTS OF DOCTORS' NAMES, ADDRESSES AND PHONE NUMBERS

10 VERSIONS CARD A

10 VERSIONS CARD B

Please check the materials right away to make certain you have everything you should have. If anything is missing, call us right away and we will advise you as to how to proceed.

Janet Bernstein
Assistant Field Director
HARRY HELLER RESEARCH CORP.
358 MAIN STREET
PORT WASHINGTON, NY 11050
(516) 883-4521

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Plaintiff's Exhibit 66

BACKGROUND

This is a study to be done with doctors and their patients. The purpose of this study is to elicit from the persons we will be interviewing certain information about drug products.

The study consists of 3 steps.

1. Screening doctors on the phone to set up an appointment with them
2. Interviewing them in their office
3. Obtaining names and addresses of certain patients and going to their homes to interview them

MATERIALS AND PROCEDURE

You have been sent the following materials:

- A list containing doctors names, addresses and phone numbers
- One unlabeled plastic bottle containing 4 different colored capsules, 3 of each of the following colors: all blue, brown/white, blue/red and maroon/white.
- 3 plastic bottles, each one containing red/blue capsules identified on the label as Cyclandelate 400 mg.
- 3 plastic bottles, each one containing blue capsules identified on the label as Cyclandelate 200 mg.

Each doctor sees only the unlabeled plastic bottle containing 3 each of the 4 different colored capsules.

Each patient sees either 3 bottles identified as Cyclandelate 400 mg or 3 bottles identified as Cyclandelate 200 mg. Which ones to show to whom are covered in the interviewer instructions.

It is ESSENTIAL that the interviewer, in the course of screening and interviewing, follow the wording set forth for her and read VERBATIM. This is vital to the success of any study and even a slight deviation could cause tremendous problems. Therefore we cannot repeat enough that proper procedures must be adhered to. We must be secure in the knowledge that this is being done and we rely on you to impress your interviewers of this. The list of doctors should be arranged in clusters as this is most efficient as well as economical. You may want to cluster the lists of doctors names by area for the interviewer or she can cluster them for herself whichever you prefer. By calling several doctors in the same area on a given day, she might be fortunate enough to have 2 or 3 interviews in the same area on one day.

If you have an interviewer who is especially good in doing this type of phone call - you can have her do the calling and another interviewer do the actual personal interview.

Please instruct the interviewer in the things she can and can't do.

She can, if the doctor questions the nature of the study, simply tell him it involves questions about drugs that a doctor prescribes.

She can tell him that she is not selling anything.

She can tell him that she has been interviewing other doctors in the area and would like his cooperation. Maybe he is the type that wants to be one of the crowd.

She can tell him she will pay him what his fee normally is for an office visit.

She can tell him if he asks why the interview can't be done over the phone that she has been instructed to do it in person and her job depends on her following her instructions.

She can if the nurse were to tell her that the doctor can't see her until next week offer the nurse $5.00-$10.00 if she would squeeze her in sooner.

She can't tell the doctor or nurse anything else.

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Plaintiff's Exhibit 66

QUOTA

Your total quota is _____ doctor interviews and _____ patient interviews. Each doctor who completes an interview must come from your list of doctors names and each patient you interview must come from the list of names the doctor or his nurse supply you with.

Not every doctor will give you the names of his patients but hopefully there will be doctors who will give you 2 or 3 names. You can use as many patient interviews from one doctor as he will give you names for. There is no quota of patient interviews per doctor, only overall.

We cannot switch our quota of doctors from one city to another but we can switch our patient quota so if your interviewer finds she is having difficulty obtaining patient names or if she is one of the lucky ones and finds she will have an overabundance of patient names, do let us know and we will see if we can either take some of your patient quota away or if another city is having problems with their quota, add to your patient quota.

GENERAL

At one point during the interview with the patient, the interviewer will ask to see the medication that the doctor prescribed which the patient told her looks like the medication in the bottle shown. If the label on the prescription says Cyclospasmol but the name Ives does not appear on every capsule have the interviewer call you immediately after the patient interview has been completed giving you the patients name, address and phone number and the name of the doctor who prescribed the medication and the name that was on the capsules that was not Ives. You in turn must call us immediately giving us this information. Even if every capsule has the name Ives except one we want to know about it. We are not interested in whether the colors are not the same, only if the name is not Ives.

BRIEFING AND QUALITY CHECK

The interviewer is to be personally briefed. The interview is not difficult but following the proper procedures, reading VERBATIM and not supplying any information other than what we have specified is of the UTMOST IMPORTANCE as previously stated.

Be sure to have them record in ink, not pencil. We know that this is one of the 7 deadly sins of interviewing but for this study it is a requirement.

Please be sure to check the interviews for legibility and for proper probing and completeness. We always emphasize legibility because if the information recorded cannot be deciphered, the work might just as well not have been done. Be sure to stress this in your briefing. Of course, all work should be checked throughout the job to see that quality is maintained.

SCHEDULE AND RETURNING THE WORK

The work is scheduled to begin as soon as you receive these materials. We estimate it should be completed by December 15th at the latest. If you cannot keep to this schedule please let us know.

Because time is so crucial to this study, whenever you have 3 or 4 interviews send them to us. However we are relying on you to use your good judgement. If having the interviewer make a trip into your office to bring you work upsets her schedule and would prevent her from keeping an appointment - we will wait another day for the interviews. You cannot send us any doctor interviews until you are completely finished with them. By this we mean if you have to call the doctors office again to obtain the names of his patients, please hold onto that interview. The only doctors interviews you can send us are those where the doctor won't give you any names or those that already have given you the names. Of course you can send us patient interviews at any time you complete them. Send the work via Federal Express Priority #1, collect and bill it to our number which is 117-0373-8. In the space provided for reference number please be sure to fill in our job #X9624.

Please staple the screener to the doctor questionnaire.

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Plaintiff's Exhibit 66

VALIDATION

Use the forms we have supplied – a separate one for the doctors and one for the patients. Don't hold the work or the forms for validation. Do make duplicate copies of the forms and send us a copy with the last of the work.

For your validation, use lines A and D only. Use A first and then D if you find A insufficient. Of course, list every completed interview.

Please record name, address and phone number, date of interview and length of interview.

Be sure the interviewer's name is indicated at the top of the form and that city, state and our job number 19624 is also filled in.

Please validate 2 interviews from each quota (doctors and patients).

If there are any discrepancies, let us know right away.

Validate the procedural things such as seeing capsules and being asked to identify them.

REPORTS

Everyone connected with this study will be anxiously awaiting the results. After 2 full days in the field please call us with a report of your progress; appointments made, doctor interviewers completed, patient interviews completed (and/or appointments set up), as well as any problems you may wish to discuss.

We appreciate your efforts in getting this challenging job done correctly and speedily.

IMPORTANT

Card A is the card shown to the doctors and Card B is the one shown to the patients. There are 10 versions for doctors and 10 versions for patients. The purpose being to affect a rotation of the products listed to prevent an order bias. Each doctor sees only one version of Card A and each patient sees only one version of Card B.

We must know in what position Cyclospasmol appeared on the card each respondent used (Doctor and Patient). There is a space provided on the doctor section the patient interview for you to put this number in. The number you are to write in is the number that is printed next to the product Cyclospasmol.

In your city, start with the card that has Cyclospasmol on your list.

Best Copy Available

PLAINTIFF'S EXHIBIT 67

HMR #X9624

INTERVIEWING INSTRUCTIONS

DOCTOR STUDY

BACKGROUND

The purpose of this study is to elicit from the persons we will be interviewing, certain information about drug products.

This will be done in 3 steps.

1. Calling doctors to set up appointments
2. Doing the personal interview with doctor's who agreed to participate
3. Obtaining names of patients from these doctors to interview these patients in their home

GENERAL PROCEDURE FOR THE QUESTIONNAIRE

Everything must be recorded in ink, not pencil.

Be sure to read each question to a respondent exactly as it is written. Do not change any words and do not paraphrase. Questions should be asked in the order they appear on the questionnaire. There should not be any explanation, interpretations or additions to a question. If a respondent does not understand a question, merely re-read it. Do not explain it.

Do not speculate about any of the answers with any respondent, nor give any hints or suggest that you have any idea whether a respondent's answer is right or wrong. This is not a test and indeed there are no right or wrong answers. Nor are there any expected answers. A "don't know" is a perfectly acceptable answer, so no respondent should be forced to guess.

Please be as full and accurate as possible in recording respondents' answers to the questions in this questionnaire. If necessary, use the back of a page for writing out answers that are so lengthy that you do not have enough room in the space provided under any question. If a respondent wants to change any answer, never cross out or erase. Simply record the new answer in detail at the place in the questionnaire where the respondent mentions it. Again, use the reverse side of the page, if necessary.

We must be secure in the knowledge that our instructions are being followed to the letter.

TO AID YOU IN TALKING TO RESPONDENTS, CYCLOSPASMOL IS PRONOUNCED CY-CLO-SPAZ-MOL.

SCREENING QUESTIONNAIRES

You have been given a list of doctors with their addresses and telephone numbers and a "Physician Screening Questionnaire". Please telephone each doctor on your list and make an appointment to interview him or her. If you need to make notes (concerning when to call back, etc.) write them on your list along side his name. In telephoning you MUST use only the procedures set forth in the "Physician Screening Questionnaire". This is VERY IMPORTANT. You can mention "up front" that you will pay him his normal office visit fee.

Your screening questionnaires tell you what to say if the doctor inquires about the nature of the research. In addition you can say that other doctors have been interviewed and you would like to have his cooperation as well.

In the event the doctor tells you to ask his nurse about an appointment and she says she can't fit you in this week you can tell her you will make it worth her while if she would try harder to fit you in. You may offer her $5.00-$10.00 for doing this.

Your persuasive powers are all important at this point. We know how difficult it is to get past a nurse or convince a busy doctor that he has time to see you but we have tried to make your job easier by being able to offer him his regular office fee.

PLAINTIFF'S EXHIBIT 67

Plaintiff's Exhibit 67

SUPERVISOR QUESTIONNAIRE

Reintroduce yourself to the doctor.

Q1 & 2 These are simple and straightforward questions. Simply check them one at a time. For Q2 ask the doctor for his best estimate if he can not tell you exactly what percent of his patients are male or female. Do not permit him to give a range of figures.

Q3 - 7 These questions are very important. This is where you show the doctor the capsules that are in the actual 50 capsule bottles. These must not be shown to the doctor on a desk or table. If he says he does not recognize any of them, skip to Q8. If he says that he does recognize them, ask Q.5 - 7. Q5 is asked in relation to his answers in Q4. Thoroughly probe any vague references to shape, size, appearance, etc.

If respondent said yes in Q4, recognized either the all blue or blue/red in Q5 or said Cyclospasmol in Q7 skip to Q10. All others ask Q8.

Q8 Hand the respondent Card A. You must show a different version of this card to each doctor you interview taking care you note in the space provided the number that is printed next to the product Cyclospasmol on the Card he sees.

If the answer is "yes" ask Q9. If it is "no",skip to Q10.

Q9 You may have more than one answer here.

Q10 This is a very important question. If the doctor says "no" skip to the last page and thank him for his help. If he says "yes" ask Q11 and 12 and record in the appropriate box.

Q13 This question is very critical to the study. It is where you ask the doctor the names of his patients for whom he prescribes Cyclospasmol. Be sure to read the explanation VERBATIM from the questionnaire. DO NOT change any words and do not paraphrase. As you can see, once again your persuasive powers are all important. It is very important that we obtain as many patient names from as many doctors as we can because you are sure to find 1 or 2 doctors who are unable to or will not give you any names at all.

Q14 Although it is important that every answer be recorded, please be especially careful in this question that the physician does not omit giving information about the dosage prescribed for each patient named.

If a physician cannot supply you with names and dosage forms prescribed for each patient at the time of the interview, please arrange to telephone his office for the list at a given time either later in the same day or on the next day. Indicate on the questionnaire that the information as to names and dosages was not obtained during the interview, but by telephone afterwards and record (1) the date when the names and dosages were obtained and (2) the identity of the persons who gave the information to you by telephone.

Thank the doctor for his help and cooperation. Give him and/or his nurse the few requested, indicating the amount on the last page of the questionnaire. Sign your full name, no initials and the date of the interview. Indicate the date of callback for patient names and the name of the person giving the names where necessary.

PATIENT INFORMATION

During patient interviews, you will need only a Patient Questionnaire and a set of either the three bottles of 200 mg. or a set of three bottles of 400 mg. cyclandelate. You must be very careful that the set shown the patient is not mixed, with some 400 mg. and some 200 mg. bottles. In determing which set to use with a given patient, select that dosage (200 mg. or 400 mg.) which the physician has indicated he or she has prescribed for that patient (Physician's Questionnaire Q12).

Some of the patients interviewed may be very elderly and/or disoriented. If the patient appears incoherent or unable to understand the questions, terminate the interview and note the reasons for termination on the Questionnaire.

Fill in all required information at the top of the patient questionnaire, making sure to indicate the Cyclospasmol dosage indicated by the doctor.

Best Copy Available

Plaintiff's Exhibit 67

Q1 "X" the proper box. The answer to this question could very well be "no". If so, skip to the instructions before Q2. If the answer is "yes" recite exactly what the patient was told, pausing to make sure the patient tells you anything and everything at all that he remembers about this.

Now you remove from your bag the 3 prescription bottles and place them before the respondent. Please be sure to indicate the appropriate design (each the bottles you are using) the bottle has a white cap, the second bottle has a brown cap and the third has a white and green cap.

Q2 The respondent is to remove the cap from each of the 3 bottles himself and place it next to the bottle. If he can't figure out how to open it you may assist him.

Q3 If the respondent does not recognize the capsules X the box next to "no" and skip to Q6a. If he does, X the "yes" box and ask Q4.

Q4 This is asked in relation to his answer to Q3. We want to know how he recognizes them, color, shape, whatever.

Q5 Record the name of the medication. A "don't know" is an acceptable answer to.

If a respondent did not recognize the capsules in response to Q3 or if did not furnish the name Cyclospasmol in response to Q5 ask Q6. All others skip to Q8a.

Q6 Hand the respondent Card B. You must show a different version of this card to each patient you interview making sure you note in the space provided the number that is printed next to the product Cyclospasmol on the card he sees. If the answer is "yes" ask Q7. All others skip to Q8a.

Q7 Record whatever the respondent tells you.

Q8a&8b These are simple and straightforward questions. Simply take them one at a time and follow the skip.

Ask the respondent to show you his bottle of medication that is like the medication you've shown him.

If the patient expresses concern that the medication is being inspected because there is something wrong with it, please reassure the patient that we merely want to record what is on the label and what markings are on the capsule, and that this does not mean there are any quality problems.

Q9 & 10 "X" one answer for each of these questions. Be sure to find out how it was changed or in what way they are different if the answer is "no" for either or both questions. Specifics are very important.

Q11 This question requires that you record all the information shown on the label of the bottle containing the patient's medication. Be sure the information you record is complete as called for on the questionnaire.

Q12 It is not necessary for you to handle the capsules in order to look at them as instructed. These capsule bottles usually have white plugs. Simply turn the bottle on its side and jiggle the capsules around so that you can see if there is a name printed on the capsule. Ask if you may pour them on a plate and afterwards the respondent can put them back in the bottle.

If the name Cyclospasmol appears on the label of any of his medication but the capsules in the bottle do not have the name IVES imprinted on them, count how many capsules are like this and call your supervisor immediately after the interview with the patient has been completed. Do this even if only one or two of the capsules do not have the name IVES on them. We must know if all the capsules bear the same name or no name.

Record all the information asked for leaving nothing unanswered.

Q13 Try to get the patient to answer this question to the best of his ability. Record everything he says.

Q14 Record the amount taken daily.

Q15 Record his answer and thank him for his time. You must print and sign your full name, not initials and record the date of the interview.

Best Copy Available

Plaintiff's Exhibit 67

Note that the General Procedure for the doctor interview applies to the patient interview too so be sure to review it carefully.

If you run into a problem for which we have not provided instructions do not attempt to solve it yourself. Do CALL your supervisor and she in turn will call us. We do not want ANYONE making their own decisions.

We have used the gender "him" when referring to a doctor or a patient for easier reference. Of course, you could be talking to either a male or female.

Thank you for your cooperation in this.

Best Copy Available

Plaintiff's Exhibit 67

ADDENDUM

In Q.9 of the Physician's Questionnaire be sure to write in the name he gave the capsule and the number that appears next to the name on the card. If he said All Blue, what name did he give it? If he said Blue/Red, what name did he give it?

PLAINTIFF'S EXHIBIT 82000

Plaintiff's Exhibit 82000

FRED'S DRUGS
Full Name of Pharmacy

204-9 Hillside Av.
Street Address

Hollis, NY. 11423
City and State

Nov. 17-1979
Date of Shop

9:40 Am
Time of Shop

CARL KITTELBERGER
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

   Yes ✓

   No _____

   Other comments This is the generic

2. After you leave the pharmacy:

   a. Do not open the container. Seal the top with tape and initial the tape.

   b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

   _____

   _____

   _____

79

PLAINTIFF'S EXHIBIT 82000

Carl Kittelberger
Shopper's Signature

Plaintiff's Exhibit 82000

Free Delivery • Open 7 Days

FRANHILL DRUGS INC.

204-19 HILLSIDE AVE. HOLLIS, N. Y. 11423

HO 5-2121

SOLD BY DATE 11/17 1975

CUSTOMER Brenda Spencer

85-06 244 St

QTY.	DESCRIPTION	PRICE	AMOUNT
	670 441		5 25
	Drugs		
	Paid		
	TOTAL		

PLATPAKIT 5 MOORE BUSINESS FORMS, INC.

109902

Plaintiff's Exhibit 82000

TEL. DEWLY 9-1877

REG. NO. 118046
BNDD AR 6784828

CARMELO C. RUIZ, M. D.

1497 OCEAN PARKWAY BROOKLYN, N. Y. 11230
CORNER AVE. O

OFFICE HOURS: BY APPOINTMENT

NAME KAY BRADY AGE

ADDRESS DATE

℞

Cyclosparmed
2002

$ 60

7 Gms

Dispense as Written

Substitution Permissible

This prescription will be filled generically unless the physician signs on the line stating "Dispense as Written".

May Be Repeated.....Times

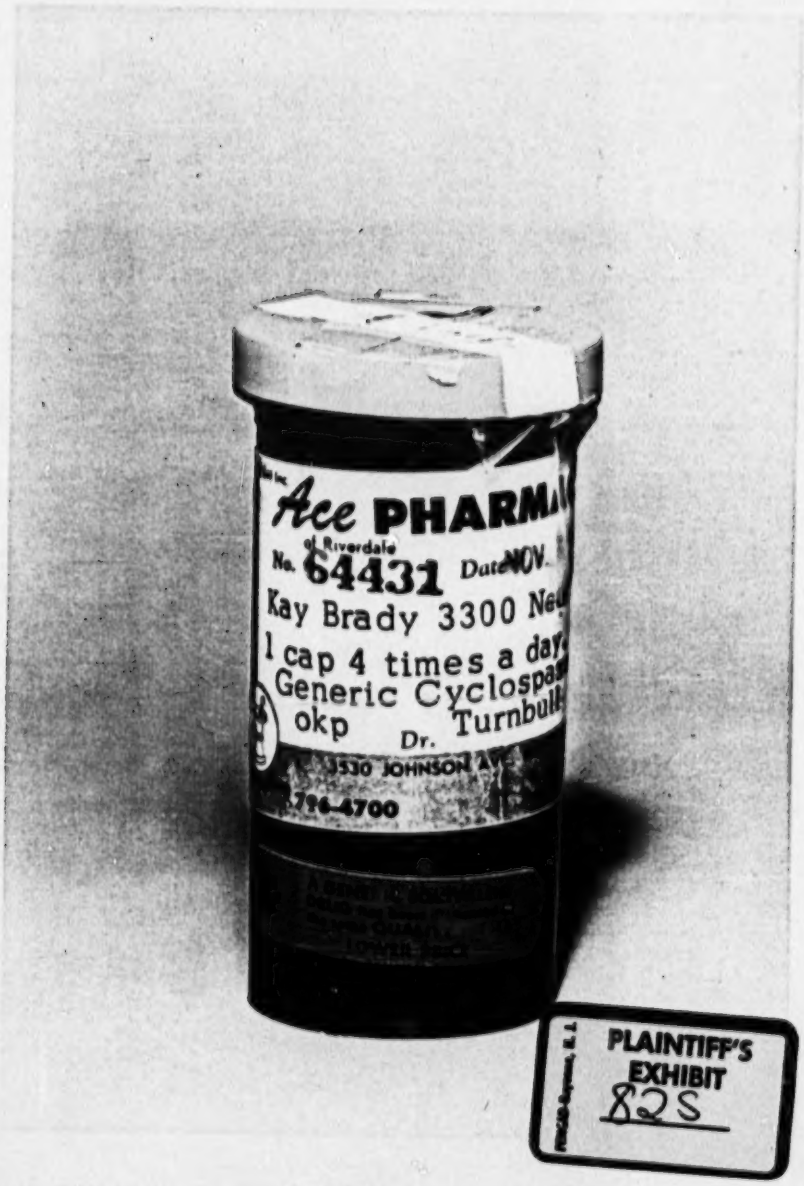
11/17/79

Franklin Drugs Inc.
204-19 - Hillside Ave
Hollis, Ny. 11423

$5.5

Carl Kittelberger

PLAINTIFF'S EXHIBIT 82S



Plaintiff's Exhibit 82S

ACE
Full Name of Pharmacy

11/12/74
Date of Shop

3530 JOHNSON Ave.
Street Address

Time of Shop

RIVERDALE N.Y. 10463
City and State

SANDER ELSNER
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

   Yes _____

   No _____

   Other comments Generic was dispensed

2. After you leave the pharmacy:

   a. Do not open the container. Seal the top with tape and initial the tape.

   b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

PLAINTIFF'S EXHIBIT 82S

Shopper's Signature

697a

Plaintiff's Exhibit 82S

RPM S. NEIER, B. S.

ACE PHARMACY

OF RIVERDALE, INC.

3530 JOHNSON AVENUE - BRONX, N. Y. 10463

Tel. 796-4700

DATE 8-12 1979

Kay Brady

JX	64431	2	D
	Henry Capsolo		
	Tumbell		
	Paid		

Plaintiff's Exhibit 82S

TELEPHONE: 798-9583

LIC. NO. 75[illegible]
BNDD REG. NO. AT [illegible]

Rudolph Turnbull, M. D.

OFFICE HOURS:
DAILY 12-2 & 5-8 P. M.
NO HOURS WEDNESDAY
SATURDAY 12-2 ONLY

1170 EAST 225TH STREET
BRONX, N. Y. 10466

NAME Ray Brady AGE [illegible]

ADDRESS 3[illegible] Netherland. Ave DATE 10/30/71

℞

Cyclospasmol - 200 mg
#40

Sig: 1 cap [illegible]

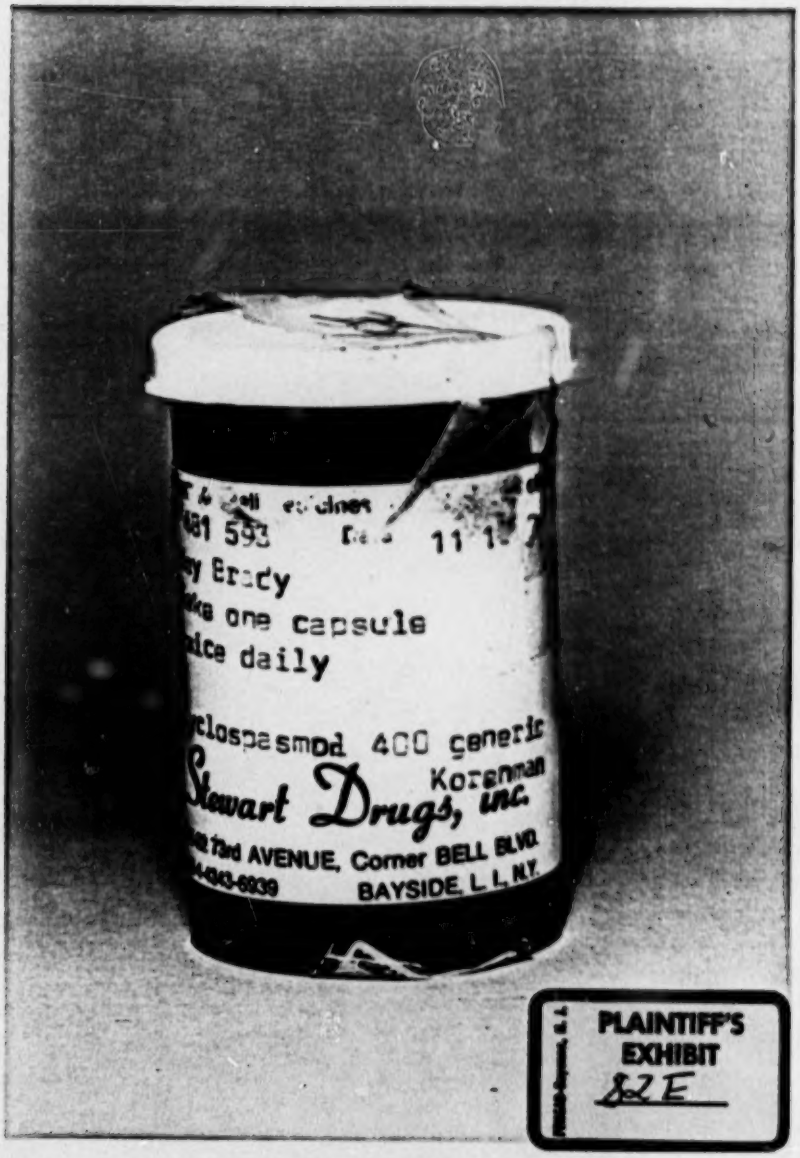
[illegible] M. D. [illegible] M. D.

DISPENSE AS WRITTEN SUBSTITUTION PERMISSIBLE

This prescription will be filled generically unless the physician signs on the line stating "Dispense as Written."

REPETATUR ( ) TIMES NON REPETATUR

PLAINTIFF'S EXHIBIT 82E



Plaintiff's Exhibit 82E

STEWART DRUGS, INC.
Full Name of Pharmacy

11/10/73
Date of Shop

215-27 [illegible] AVE.
Street Address

2:30
Time of Shop

BAYSIDE L.I. N.Y.
City and State
11364

SANDRA EISENBERG
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

   Yes _____

   No ✓

   Other comments PARTIAL RX - OUT OF STOCK
   ASKED TO COME BACK TUES.

2. After you leave the pharmacy:

   a. Do not open the container. Seal the top with tape and initial the tape.

   b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

_____

_____

_____

PLAINTIFF'S EXHIBIT 82E

[signature]
Shopper's Signature

Plaintiff's Exhibit 82E

CERTIFIED RECEIPT

Date ..... 197..

B No. 48153 $ 2.45

B No. ..... $ .....

B No. ..... $ .....

B No. ..... $ .....

B No. ..... $ .....

Total $ .....

For King Bed

.....

Dr. .....

STEWART DRUGS, Inc.
215-22 73rd AVENUE
BAYSIDE, L.I., N. Y. 11364
HOllis 4-4343-6939

STEWART DRUGS, Inc.
215-22 73RD Ave.
BAYSIDE, L.I. N.Y.
11364

Plaintiff's Exhibit 82E

881-7922 BNDD No. AK180491

GARY KORENMAN, M.D., P.C.
(NEUROLOGY)

799 PARK AVENUE NEW YORK, N. Y. 10021

NAME Kay Brady AGE adult

ADDRESS 307 Prospect Gt. Nk DATE 11/5/79

R

Cyclospasmol 400

#60

TBID

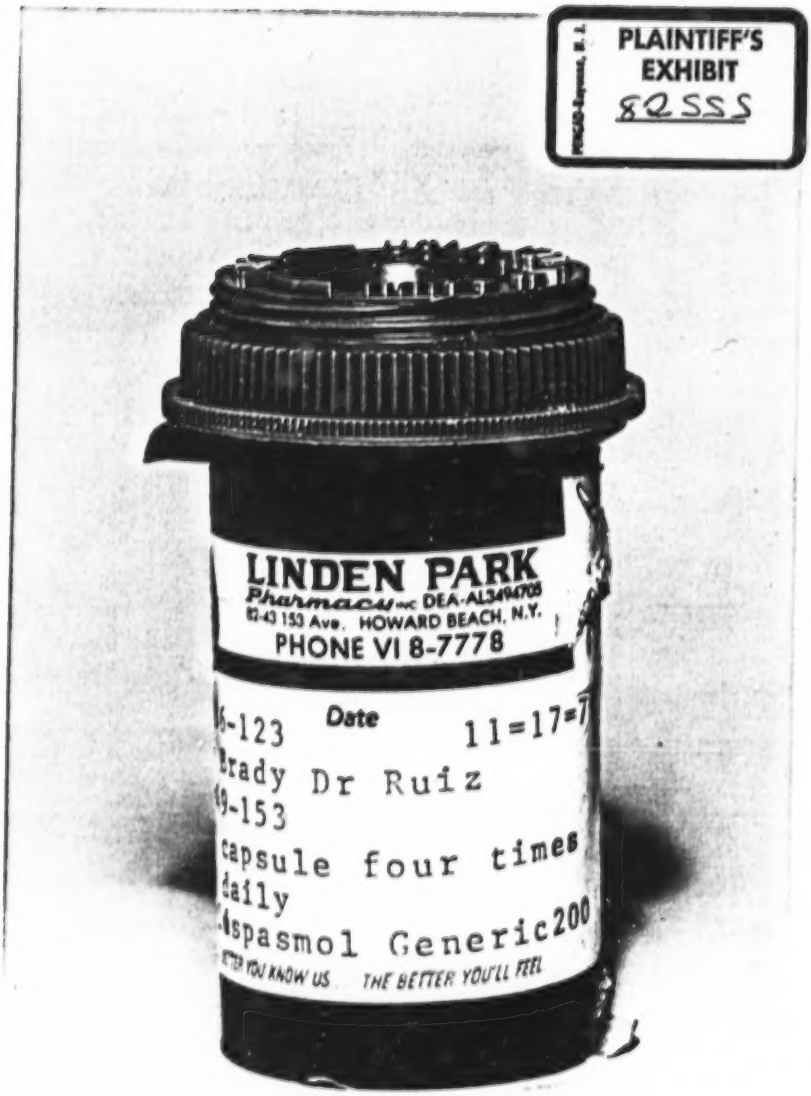
REFILL 0 1 2 3 4 5 6

DISPENSE AS WRITTEN

SUBSTITUTION PERMISSIBLE

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS THE PHYSICIAN SIGNS ON THE LINE STATING DISPENSE AS WRITTEN

PLAINTIFF'S EXHIBIT 82SSS



Plaintiff's Exhibit 82SSS

Linden Park Pharmacy
Full Name of Pharmacy

8243 - 153 Ave
Street Address

Howard Beach, N.Y. 1414
City and State

Nov. 17. 1979
Date of Shop

3:30 PM
Time of Shop

CARL KITTELBERGER
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

Yes ✓

No _____

Other comments That's it

2. After you leave the pharmacy:

a. Do not open the container. Seal the top with tape and initial the tape.

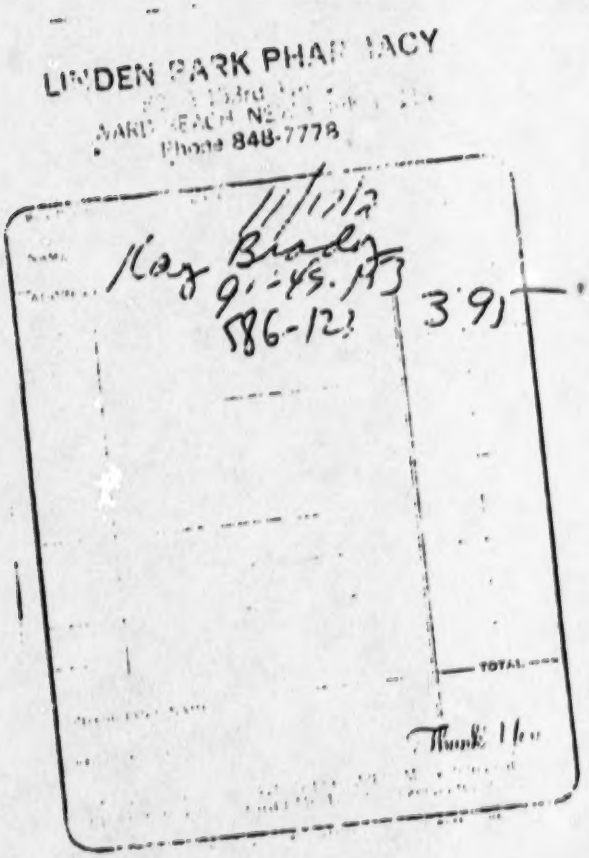
b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

PLAINTIFF'S EXHIBIT 82SSS

Carl Kittelberger
Shopper's Signature

Plaintiff's Exhibit 82SSS



706a

Plaintiff's Exhibit 82SSS

[illegible]/79
[illegible]den Park Pharmacy
[illegible]2-43-153rd Ave
[illegible]rand Beach, [illegible] 11414

[illegible]
[illegible] Kittelberger

TEL. DEWEY 9-1877

REG. NO. 118046
BNDD AR 6784828

CARMELO C. RUIZ, M. D.

1497 OCEAN PARKWAY BROOKLYN, N. Y. 11230
CORNER AVE. O

OFFICE HOURS: BY APPOINTMENT

NAME BRENDA SPENCER AGE

ADDRESS DATE

℞

Cyclospermol 400 g

p. 60

Ons.

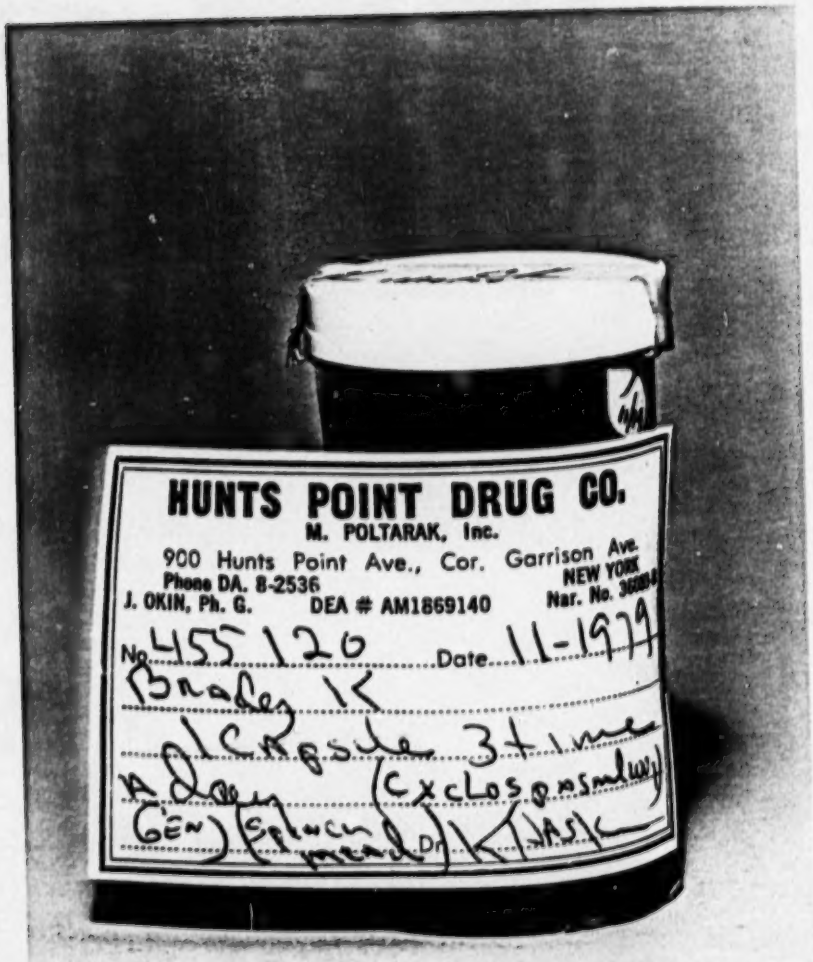
Dispense as Written

Substitution Permissible

This prescription will be filled generically unless the physician signs on the line stating "Dispense as Written".

May Be Repeated.....Times

PLAINTIFF'S EXHIBIT 82TTT



PLAINTIFF'S EXHIBIT 82TTT

Plaintiff's Exhibit 82TTT

Hunts Point Drug Co
Full Name of Pharmacy

Nov 29, 1979
Date of Shop

900 Hunts Point Av
Street Address

11:40 Am
Time of Shop

Bronx NY 10474
City and State

Carl Kittelberger
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

Yes ✓

No _____

Other comments That's what I gave you - you save $2.00 or more.

2. After you leave the pharmacy:

a. Do not open the container. Seal the top with tape and initial the tape.

b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

PLAINTIFF'S EXHIBIT 82TTT

Carl Kittelberger
Shopper's Signature

82

Best Copy Available

Plaintiff's Exhibit 82TTT

STATEMENT OF ACCOUNT WITH

HUNTS POINT DRUG CO.

M. POLTARAK, Inc. J. OXIN, Ph. G.

900 Hunts Point Ave., Cor. Garrison Ave. Phone DA. 8-2536

NEW YORK, N. Y., 11-19 19 79

K. Bradley

2552 Martha Ave

Rx 455120 $3.60

cyclandelate 200 tid

Paid

11-29-79

Hunts Point Drug Co.

Hunts Point Ave

Bronx, Ny 10474

360

Kittelberger

Plaintiff's Exhibit 82TTT

Tel 988-9515 Reg. No 123134

ALBERT KHASKI, M.D.

11 EAST 68th STREET NEW YORK, NEW YORK 10021

NAME Kris Bradley AGE Adult

ADDRESS _____ DATE 11/11/79

℞

Sclospasm of 200 & 100 tid

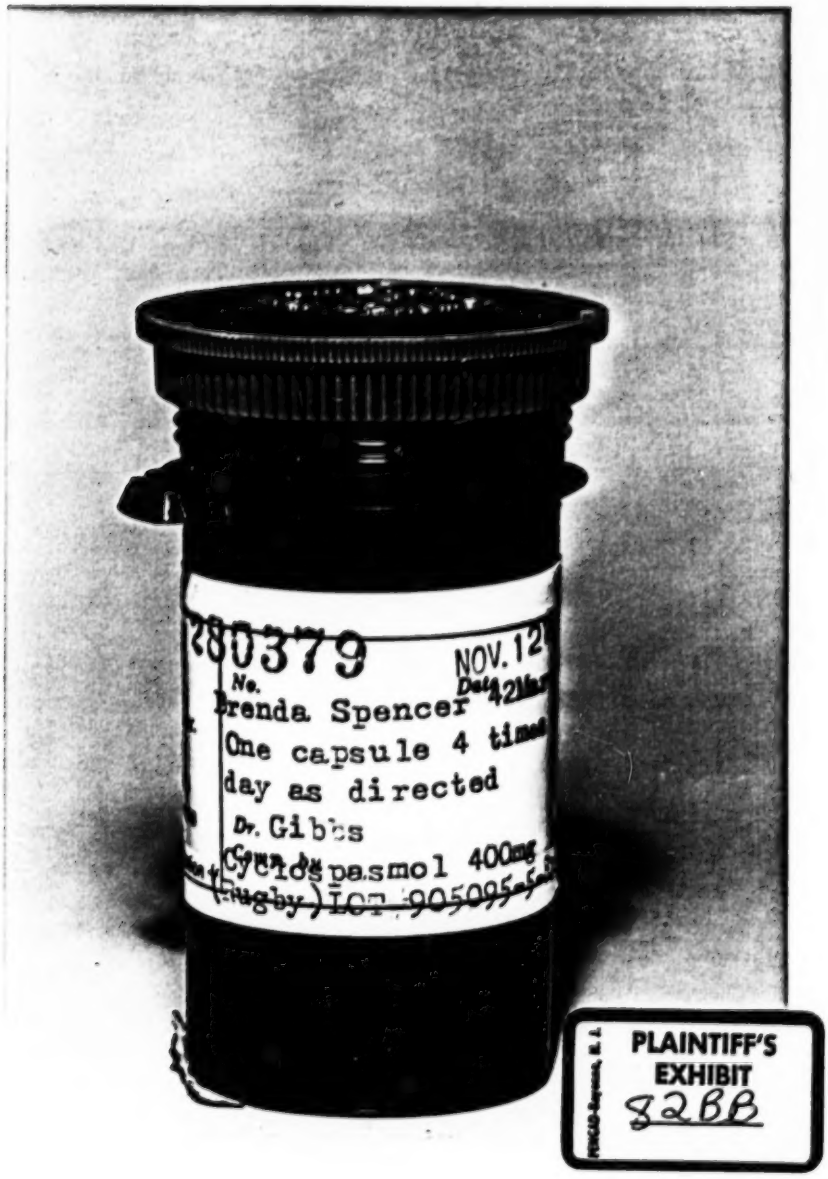
#30

Dispense As Written

Substitution Permissible

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS DOCTOR SIGNS ON LINE STATING DISPENSE AS WRITTEN

PLAINTIFF'S EXHIBIT 82BB



Plaintiff's Exhibit 82BB

ARKAY
Full Name of Pharmacy

11/12/79
Date of Shop

140 DYCKMAN ST.
Street Address

Time of Shop

N.Y. 10040
City and State

SANDOR FEINBERG
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

Yes _____

No _____ Rx

Other comments GENERIC WAS GIVEN DUE TO LOWER COST.

2. After you leave the pharmacy:

a. Do not open the container. Seal the top with tape and initial the tape.

b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

PLAINTIFF'S EXHIBIT 82BB

Shopper's Signature

Plaintiff's Exhibit 82BB

Patient.....
Address.....
Apartment.....
Doctor.....
Time Rec'd.....
Promised.....
Price.....
Call.....
Deliver.....
Paid.....

№ 26968

Plaintiff's Exhibit 82BB

FRANTZ GIBBS, M.D.

2070 Grand Concourse
Bronx, New York 10457 Tel: (212) 731-5347

NAME Brenda Shuree AGE

ADDRESS 42 Macy St Bx DATE 10.29.99

℞ *This prescription will be filled generically unless physician signs on line stating "dispense as written".*

Cyclosporine 100mg #60

REFILL:
1 2 3 4 5 NR
☐ ☐ ☐ ☐ ☐ ☐

DISPENSE AS WRITTEN M.D. SUBSTITUTION PERMISSIBLE M.D.

DEA/REG No. [illegible] PRINT NAME M.D.

Plaintiff's Exhibit 82A

DRUG Co. Inc

Drug Pharmacy
Full Name of Pharmacy

12/2/75
Date of Shop

117 Rockaway Ave
Street Address

11:55
Time of Shop

Valley Stream L.I.
City and State

Sandra Ellenberg
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

Yes ✓

No _____

Other comments Dispensed Generic Cyclandelate

2. After you leave the pharmacy:

a. Do not open the container. Seal the top with tape and initial the tape.

b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below.

Cyclospasm is 3 times more expensive than generic

PLAINTIFF'S EXHIBIT 82A

Sandra Ellenberg
Shopper's Signature

Plaintiff's Exhibit 82A

RECEIPT
FOR PRESCRIBED MEDICINES

ORSO DRUG CO. INC.
E. HAUPTMAN Pharmacist
117 ROCKAWAY AVENUE
VALLEY STREAM, L. I., N. Y.
FREE DELIVERY - VA 5-0671

Save For Your Tax Records
Keep for Six Years or More

For Brenda Spencer
Address
Doctor
℞ No. 630012 Price 5.45
℞ No. _____ Price _____
Price
_____ Price
SALES TAX (If Any)
Date 14/2/79 Total 5.45
Signed J R Colman

[illegible] ENDICOTT, N. Y.

Plaintiff's Exhibit 82A

MOHAWK 9-3420 REG. NO. AN0772512

K. CALVIN NICHOLAS, M.D., P.C.

91 LITTLE EAST NECK RD. S. BABYLON, NEW YORK 11702

NAME Brenda Spencer AGE

ADDRESS DATE 11-15-79

℞

Cyclospasmol
400 mg
#60

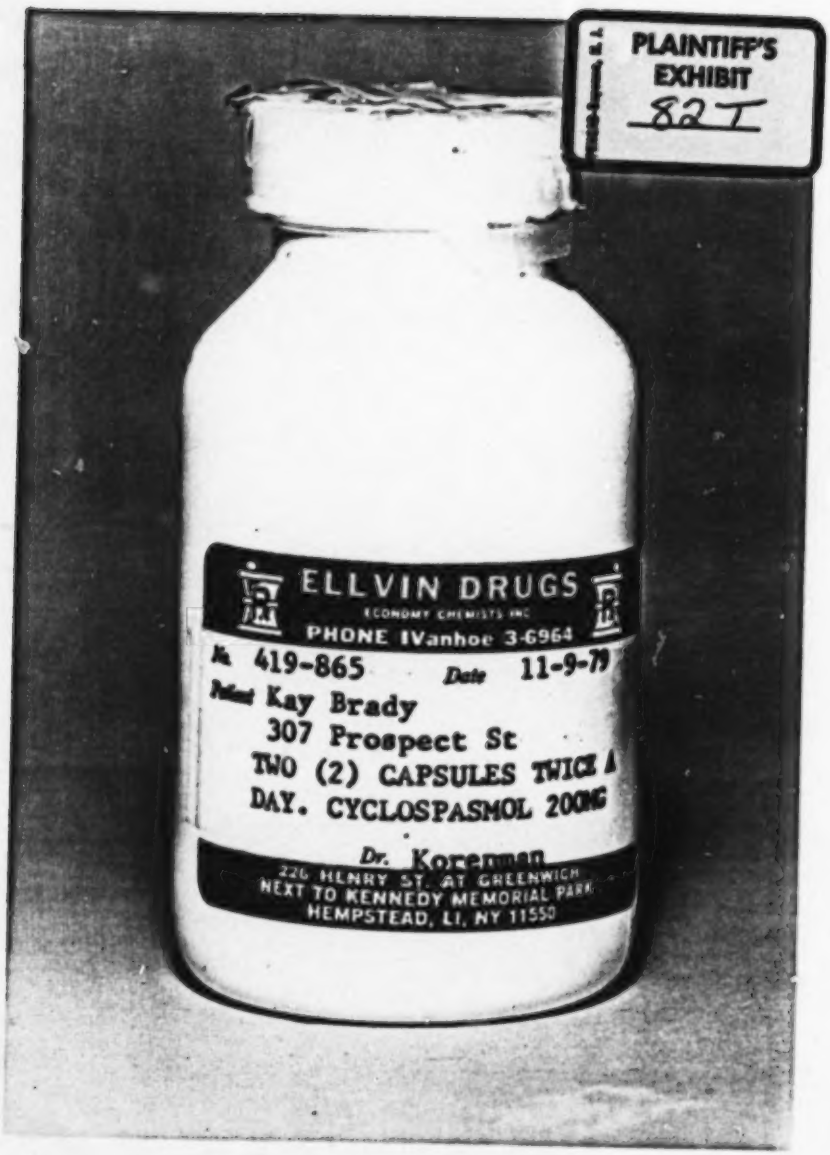
1 B.I.D.

REFILL 5X Nicholas

DISPENSE AS WRITTEN SUBSTITUTION PERMISSIBLE

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER SIGNS ON THE LINE STATING "DISPENSE AS WRITTEN."

PLAINTIFF'S EXHIBIT 82T



Plaintiff's Exhibit 82T

Ellin Drugs — 11/9/09
Full Name of Pharmacy — Date of Shop

226 Henry St. — 4:15
Street Address — Time of Shop

Hempstead, L.I. N.Y. 11550 — Sandor Fuenberg
City and State — Shopper's Name Printed

1. After the pharmacist has filled and given you the prescription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

Yes _____

No _____

Other comments _____

2. After you leave the pharmacy:

a. Do not open the container. Seal the top with tape and initial the tape.

b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

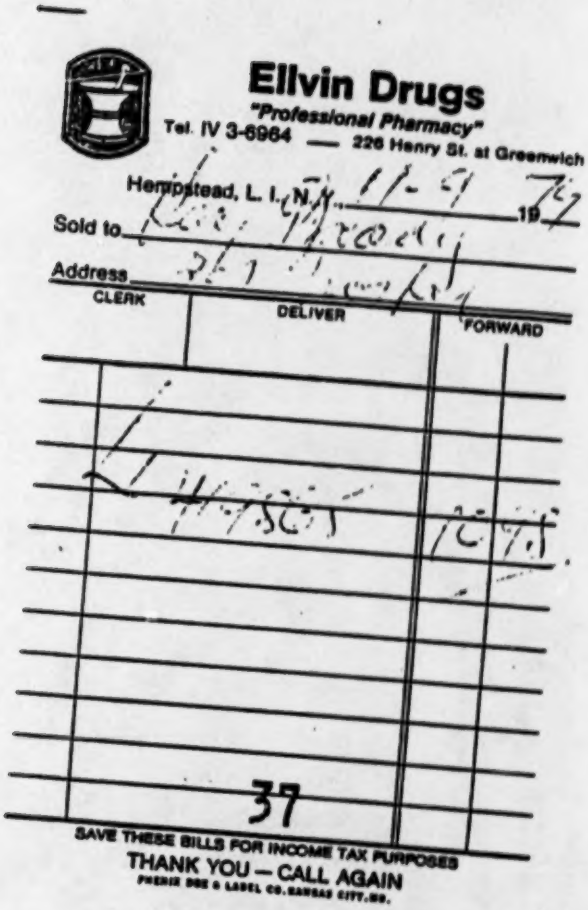
3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

He informed me that Cyclospasmol did not come in 400mg. He said he gave me a generic of 200mg to be taken according to label see label

PLAINTIFF'S EXHIBIT

Shopper's Signature

Plaintiff's Exhibit 82T



Ellvin Drugs
"Professional Pharmacy"
Tel. IV 3-6964 — 226 Henry St. at Greenwich

Hempstead, L. I., N. Y. 11-9 19 79

Sold to [illegible]

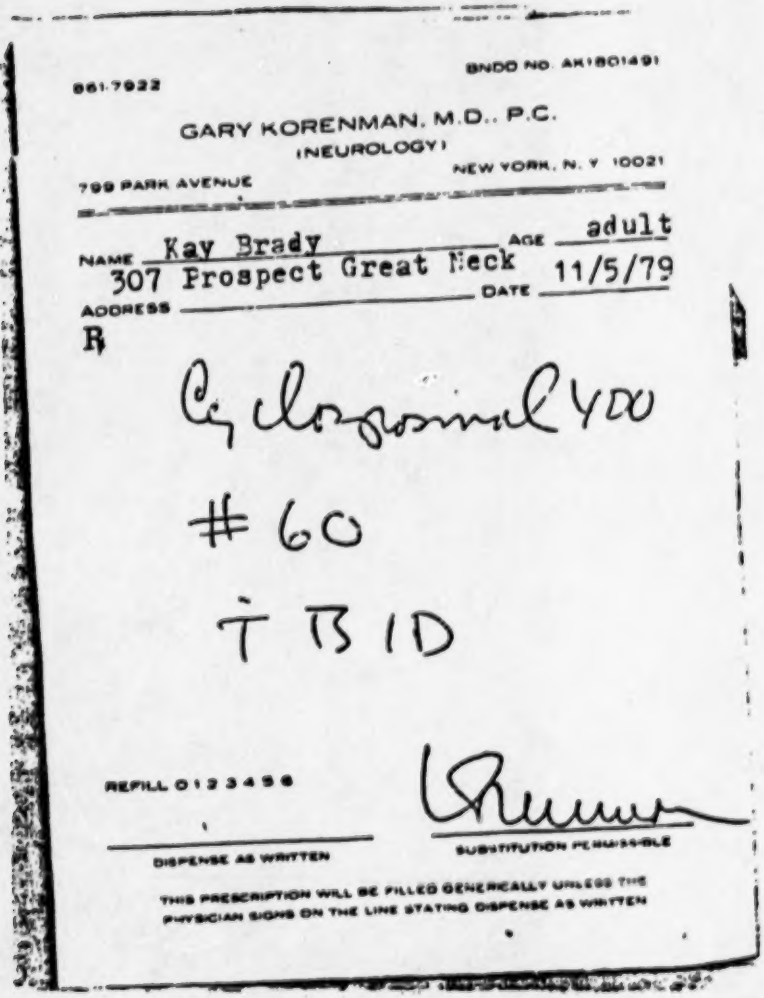
Address [illegible]

CLERK	DELIVER	FORWARD
	[illegible]	[illegible]

37

SAVE THESE BILLS FOR INCOME TAX PURPOSES
THANK YOU — CALL AGAIN
PHENIX DOE & LABEL CO. KANSAS CITY, MO.

Plaintiff's Exhibit 82T



861-7922

BNDD NO. AK1801491

GARY KORENMAN, M.D., P.C.
(NEUROLOGY)

799 PARK AVENUE

NEW YORK, N. Y. 10021

NAME Kay Brady AGE adult

ADDRESS 307 Prospect Great Neck DATE 11/5/79

R

Cyclogonal 400

#60

T BID

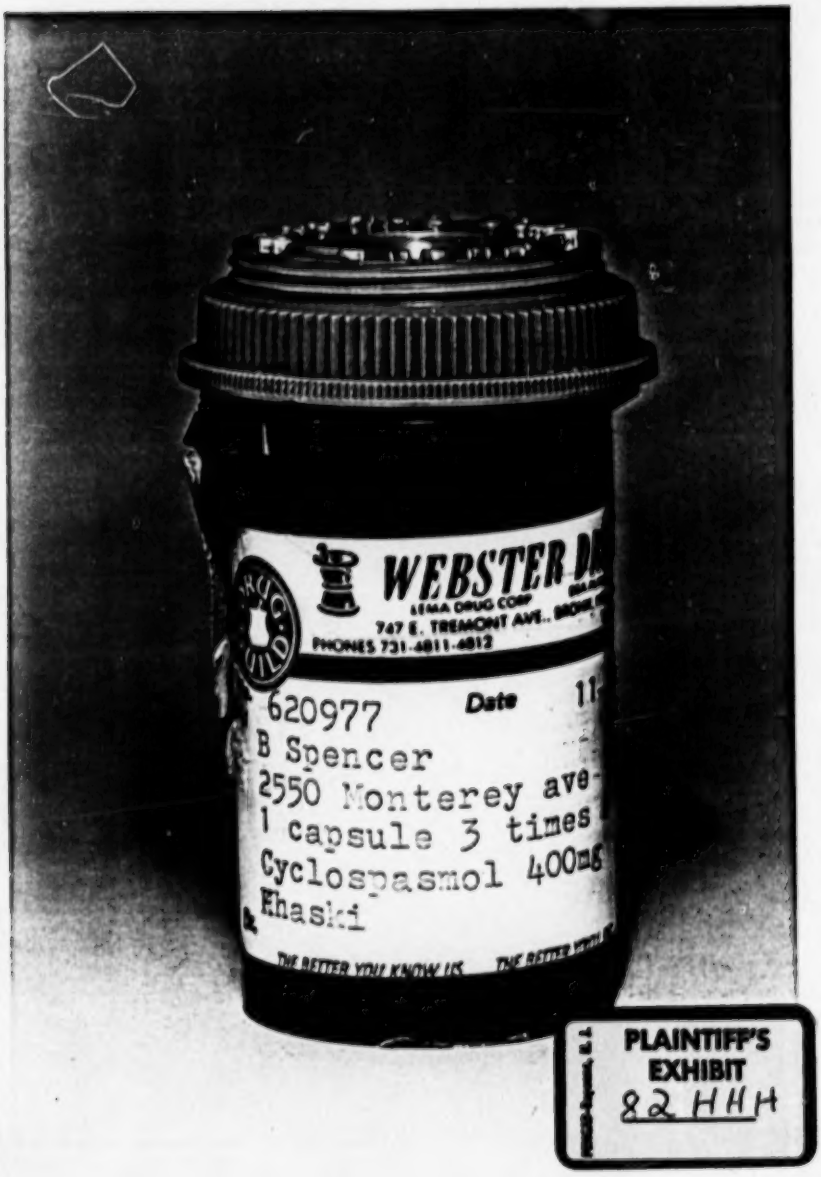
REFILL 0 1 2 3 4 5 6

DISPENSE AS WRITTEN

SUBSTITUTION PERMISSIBLE

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS THE PHYSICIAN SIGNS ON THE LINE STATING DISPENSE AS WRITTEN

PLAINTIFF'S EXHIBIT 82HHH



Plaintiff's Exhibit 82HHH

WEBSTER DRUG (Lama Drug Corp) — Full Name of Pharmacy

NOV. 19. 1979 — Date of Shop

747 E. TREMONT AV. — Street Address

11:05 AM — Time of Shop

BRONX NY 10457 — City and State

CARL KITTELBERGER — Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

   Yes ✓

   No _____

   Other comments _____

2. After you leave the pharmacy:

   a. Do not open the container. Seal the top with tape and initial the tape.

   b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

PLAINTIFF'S EXHIBIT 82HHH

Carl Kittelberger

Shopper's Signature

Plaintiff's Exhibit 82HHH

Webster Drugs & Cosmetics
"Open Every Day of the Year"
747 EAST TREMONT AVENUE - BRONX, N.Y. 10457
Phone: 731-4811

DATE 11-19-1979

M [illegible]

ADDRESS

	[illegible] 977	8	25
		8	25

OVER ONE MILLION PRESCRIPTIONS FILLED

11/19/79
Webster Drugs (Lima Drugtop)
747 E. Tremont Ave
Bronx, N.Y. 10457

8 25
Carl Kittelberger

Tel. 988-9515 Reg. No. 123134

ALBERT KHASKI, M.D.

11 EAST 68th STREET NEW YORK, NEW YORK 10021

NAME Mrs Brenda Spencer AGE Adult

ADDRESS DATE 11/12/79

℞

Sclospasmol 400 g no trd

#30

[signature] AU 6454665

DISPENSE AS WRITTEN SUBSTITUTION PERMISSIBLE

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS DOCTOR SIGNS ON LINE STATING DISPENSE AS WRITTEN

PLAINTIFF'S EXHIBIT 82DDD

(ORIGINAL EXHIBIT LOST BY
COURT OF APPEALS)

Plaintiff's Exhibit 82DDD

(Rywall Drugs)
Full Name of Pharmacy

Dec 20, 1979
Date of Shop

109-11 Washington Ave
Street Address

10 20 AM
Time of Shop

Endicott N.Y.
City and State

ALFONSO B. PASKE
Shopper's Name Printed

1. After the pharmacist has filled and given you the presecription, ask him or her if he (she) carries generic cyclandelate in the same dosage form as called for in the prescription.

Yes ✓ Pharmacist stated what he

No _____ filled the Rx with the generic drug

Other comments _____

2. After you leave the pharmacy:

a. Do not open the container. Seal the top with tape and initial the tape.

b. Place the taped container, the receipt for purchase received from the pharmacy and a photocopy of the doctor's prescription in this envelope and seal it closed.

3. If the pharmacist had any discussion with you concerning the prescription other than that recorded in (1) above, record the contents of the conversation below:

_____

_____

_____

PLAINTIFF'S EXHIBIT 82 DDD

Alfonso B. Paske
Shopper's Signature

80

OFFICIAL RECEIPT
FOR PRESCRIPTION SERVICES

LUIZZI PHARMACY, INC.
V. N. Luizzi, Ph. G.
109 Washington Avenue
Endicott, N. Y.
785-5451

Senior Citizen Discount

Save for Your Tax Records

For Brenda Spencer
Address
Doctor
℞ No. 205633 Price 4.25
℞ No. Price
℞ No. Price
Price
Price
Sales Tax
Date 12/20/79 Total
Signed [illegible]

OFFICE HOURS
BY APPOINTMENT ONLY

MICHAEL P. RIZZUTO, M.D., P.C.
Practice Limited to Surgery
609 E. Main Street
Endicott, New York

REG. NO. [illegible]
PHONE [illegible]

Patient's Name Brenda Spencer Age [illegible]
Address Date

℞

Cyclospasmal 400 mg #40
sig: T. B.I.D.

MAY BE REFILLED ____ TIMES
AS REQUESTED ☐
NON. REP. ☐

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PHYSICIAN SIGNS ON LINE STATING "DISPENSE AS WRITTEN."

_____ M.D. M.P. Rizzuto M.D. P.C. M.D.
Dispense as written Substitution permissable

728a
Plaintiff's Exhibit 82DDD

PLAINTIFF'S EXHIBIT 90

PLAINTIFF'S EXHIBIT 92

GEORGIA MEDICAL ASSISTANCE DRUG LIST
ALPHABETICAL SECTION

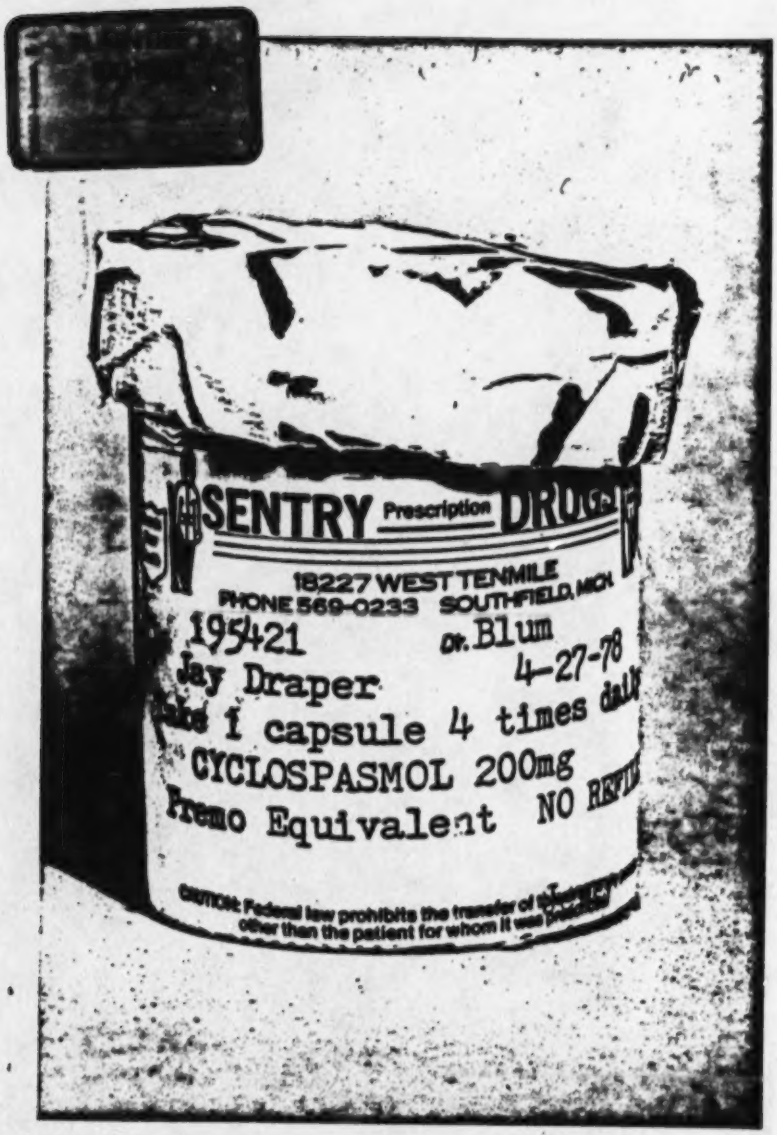
			PKG SIZE	BU	MADL
CYCLOPAR		(PARKE, DAVIS)			
0071-0407-04	CAP 250MG		100	TB	AP21
0071-0697-04	CAPS 500MG		100	TB	AP22
CYCLOSPASMOL		(IVES)			
0082-4120-01	TAB 100MG		100	TB	AP26
0082-4120-02	TAB 100MG		500	TB	AP27
0082-4124-01	CAP 200MG		100	TB	AP24
0082-4124-02	CAP 200MG		500	TB	AP23
0082-4124-04	CAP 200MG		1000	TB	AP25
0082-4148-01	CAP 400MG		60	TB	EP24
0082-4148-02	CAP 400MG		500	TB	EP45
CYDEL		(W E HAUCK)			
3797-0037-03	CAP 200MG		100	TB	FA26
3797-0037-06	CAP 200MG		1000	TB	FA27
CYLERT		(ABBOTT)			
0074-6073-13	TAB 75MG		100	TB	FJ76
0074-6057-13	TAB 37.5MG		100	TB	FJ75
0074-6025-13	TAB 18.75MG		100	TB	FJ73
CYLERT CHEW		(ABBOTT)			
0074-6088-13	TAB 37.5MG		100	TB	FJ74
CYSTOSPAZ		(CONAL)			
0061-2225-10	TABS		100	TB	AP29
CYSTOSPAZ		(WILLIAM A. WEBSTER)			
0059-2225-10	TAB 0.15MG		100	TB	AP28
CYSTOSPAZ-SR		(CONAL)			
0061-2250-10	CAPS		100	TB	AP31
CYSTOSPAZ-SR		(WILLIAM A. WEBSTER)			
0059-2250-10	CAPS		100	TB	AP32
CYTELLIN		(LILLY)			
0002-0W48-05	SUSP		PT	OZ	AP33
CYTOLEN		(LEN-TAG CO.)			
0315-0000-00	TAB 0.1 MG/TAB		2000	TB	FG96
CYTOMEL		(SMITH KLINE AND FRENCH)			
0007-0014-20	TABS 5MCG		100	TB	AP36
0007-0016-20	TABS 25MCG		100	TB	AP35
0007-0016-30	TABS 25MCG		1000	TB	AP34
0007-0017-20	TABS 50MCG		100	TB	AP37
CYTOXAN		(MEAD JOHNSON)			
0087-0504-01	TAB 25 MG		100	TB	AP38
0087-0503-01	TAB 50MG		100	TB	AP41
0087-0503-02	TAB 50MG		1000	TB	AP39
0087-0500-01	VIALS 100MG/10ML		1	AM	FD72
0087-0501-01	VIALS 200MG/20ML		1	AM	FD73
0087-0502-01	VIALS 500MG/30ML		1	AM	FD74

Plaintiff's Exhibit 92

GEORGIA MEDICAL ASSISTANCE DRUG LIST
ALPHABETICAL SECTION

		PKG SIZE	BU	MAI
CYANOCOBALAMIN	(WILLIAM S. MERRELL CO.)			
0068-0818-61	VIAL 1000MCG/CC	10ML	VI	AN9
CYANOCOBALAMIN	(ZENMER)			
0133-0119-82	VIAL 1000MCG/CC	10CC	VI	DG1
CYANOCOBALAMIN	(ZENMER CO)			
0133-0118-82	VIALS 100MCG/ML 10ML EA	1	AM	FE7
CYANTIN	(LEDERLE LABORATORIES)			
0005-5212-23	TABS 50MG	100	TB	AN9
0005-5214-34	TABS 50MG	1000	TB	AP1
0005-5213-23	TABS 100MG	100	TB	AP1
0005-5215-34	TABS 100MG	1000	TB	AP1
CYCLAMYCIN	(WYETH LABORATORIES)			
0008-0222-02	CAP 250MG	36	TB	AP1
CYCLANDELATE	(ECONO-RX)			
1233-6060-01	CAP 200MG	100	TB	FT4
1233-6060-10	CAP 200MG	1000	TB	FT4
1233-6061-10	CAP 400MG	100	TB	FT4
1233-6061-10	CAP 400MG	1000	TB	FT4
CYCLANDELATE	(GENEVA GENERICS)			
0781-2668-01	CAP 200MG	100	TB	FT4
0781-2668-10	CAP 200MG	1000	TB	FT4
0781-2670-01	CAP 400MG	100	TB	FT4
CYCLANDELATE	(SPENCER MEAD)			
0537-6053-01	CAP 200MG	100	TB	ES8
0537-6053-10	CAP 200MG	1000	TB	ES8
CYCLOGESTERIN	(THE UPJOHN COMPANY)			
0009-0016-01	TABS	15	TB	AP1
CYCLOGYC OPTH	(ALCON)			
0065-0393-02	SOL 2% W/DROPPER	2CC	EA	ED2
CYCLOGYL	(ALCON)			
0065-0391-15	OPHT SOL 1%	15CC	EA	AP16
0065-0393-07	OPHT SOL 2%	7.5CC	EA	AP18
0065-0390-15	OPHT SOL 0.5%	15CC	EA	AP17
CYCLOGYL OPHT	(ALCON)			
0065-0391-02	SOL 1% W/DROPPER	2CC	EA	ED24
CYCLOMYDRIL	(ALCON)			
0065-0358-75	OPHT SOL	7.5CC	EA	AP19
CYCLOMYDRIL OPHT	(ALCON)			
0065-0358-02	SOL W/DROPPER	2CC	EA	ED25
CYCLOPAR	(PARKE-DAVIS)			
0071-0407-32	CAP 250MG	1000	TB	FT51

PLAINTIFF'S EXHIBIT 95



Plaintiff's Exhibit 95

DR. DAVID BLUM
Foot Specialist - X-Ray Physiotherapy
15311 WEST McNICHOLS AVE.
DETROIT 35, MICHIGAN

Phone 272-4884

Office Hours Daily, Except Thurs.
By Appointment Only

NAME Jay Draper AGE

ADDRESS DATE 4-27-78.

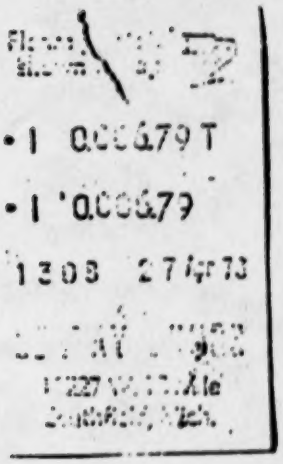
℞ Cyclosporinal 200 mg
#60
Sig: 1 Cap q i.d.

___NON-REPETATUR
___REPETATUR SEMEL
___REPETATUR BIS.
___REPETATUR EX PRAECEPTO

BHDD REGISTRATION NUMBER
AB3047758

REG. No. Harold Blum DPM D.S.C.

Plaintiff's Exhibit 95



DATE	DOCTOR	PRESCRIPTION NUMBER	PATIENT	AMOUNT
4/27/73	Blum	19542	J. Draper	679

RETAIN THIS RECEIPT FOR PROOF OF MEDICAL EXPENSE

SENTRY DRUGS

Prescriptions

"Guards Your Health-Guards Your Dollars"

STORE NO.

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	

PLAINTIFF'S EXHIBIT 95-A

Plaintiff's Exhibit 95

SHOPPING REPORT

PHARMACY Sentry Presc. Drugs CITY Southfield

ADDRESS 18227 W. 10 mile STATE Michigan ZIP 48075

*LOCATION: 1 __ 2 __ 3 __ 4 X 5 __ TYPE: SK __ K __ NK __

DATE: 4/27/78 TIME: 2:00 Pm NO. CLERKS 3 NO. CUST. 10

DESCRIPTION OF PHARMACIST:

M X F __ AGE 28 HAIR Brown

WEIGHT 155 HEIGHT 5'11

GLASSES no MUSTACHE yes

OTHER CHARACTERISTICS Name: Jerry.

DESCRIPTION OF CLERK:

M- __ F X AGE 19 HAIR Brown

WEIGHT 130 HEIGHT 5'4

GLASSES — MUSTACHE —

OTHER CHARACTERISTICS —

TELEPHONE LOC. Behind Counter USED BY PHARMACIST No

RX. DEPT. LOC. in Back NO. OF R.PH. IN RX. DEPT. 1

I handed the Clerk-Pharmacist a prescription dated 4/27/78 made out to Jay Draper for Cyclospasmol 200 mg caps by Doctor David Blum, D.P.M.

CONVERSATION:

SHOPPER - [redacted] asked if cash payment, 2nd address

[redacted] - CLERK-R.PH.

SHOPPER - CLERK-R.PH.

I paid the clerk-pharmacist $ 6.79 and received a container containin Cyclandelate 200 mg. The container bore a label with the pharmacy name and address as above. Rx number 195421.

Directions: Take 1 cap 4 times daily

DOCTOR: David Blum, D.P.M. DATED: 4/27/78

I have identified the purchase by writing my name, the name and addres of the pharmacy, time, date and price of purchase [redacted]. I sealed the container [redacted] in an envelope

DATE [redacted] Submitted.

REGISTERED NO.:

DATE RECEIVED [redacted] by [illegible] SIGNATURE Jay Draper

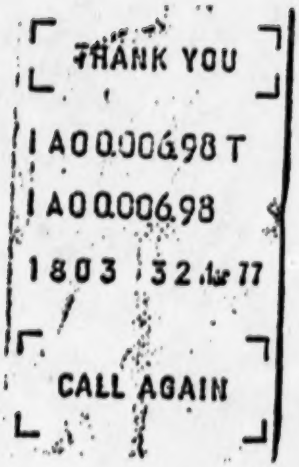
(Mail Delivery or Shopper Delivery) SHOPPER

---

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center

PLAINTIFF'S EXHIBIT 96

Plaintiff's Exhibit 96



Sparta EX 1 (1D)
4/27/78
DHD

Plaintiff's Exhibit 96

BRENTWOOD MEDICAL CENTER

18937 VAN DYKE AVENUE DETROIT, MICHIGAN 48234

HENRY C. BORIS D.O. AB 3037028 PHONE: 368-1280

PATIENTS NAME Jay W. Draser AGE

ADDRESS 7141 Shenandoah DATE 3/22/78

℞ Cyclospasmol 200 mg

#60

Label: Take cap i t.i.d

MEDICAID ID # 1254179

N.R. [ ] REFILL ____ TIMES . Henry C. Boris D.O.

Plaintiff's Exhibit 96

SHOPPING REPORT

PHARMACY MeRRill Phar. CITY DeTroiT

ADDRESS 15500 PuRiTan STATE MiCH. ZIP

*LOCATION: 1 2 3 4 X 5 TYPE: SK K NK

DATE: 3/22/78 TIME: 4:30pm NO. CLERKS 2 NO. CUST. 15

DESCRIPTION OF PHARMACIST:

M X F AGE 30 HAIR curly Black

WEIGHT 180 HEIGHT 5'11"

GLASSES NO MUSTACHE No

OTHER CHARACTERISTICS —

DESCRIPTION OF CLERK:

M- F X AGE 47 HAIR Black

WEIGHT 120 HEIGHT 5'3"

GLASSES NO MUSTACHE

OTHER CHARACTERISTICS

TELEPHONE LOC. BACK USED BY PHARMACIST NO

RX. DEPT. LOC. BACK NO. OF R.PH. IN RX. DEPT. 2

I handed the Clerk-Pharmacist a prescription dated 3/22/78 made out to Jay Draper for Cyclospasmol 200 mg by Doctor Boris.

CONVERSATION:

SHOPPER - ~~[illegible]~~ ~~[illegible]~~ None

~~[illegible]~~ - CLERK-R.PH. None

SHOPPER - CLERK-R.PH. ~~None~~ ASKED For phone NO.

I pa. d the clerk-pharmacist $6.98 and received a container containi cyc~~[illegible]~~. The container bore a label with the pharmacy name and address as above. Rx number B272 459

Directions: One cap T.I.D.

DOCTOR: Boris. DATED: 3/22/78

I have identified the purchase by writing my name, the name and addre of the pharmacy, time, date and price of purchase ~~[illegible]~~ ~~[illegible]~~. I sealed the container ~~[illegible]~~ in an envelope

DATE ~~[illegible]~~ Submitted.

REGISTERED NO.:

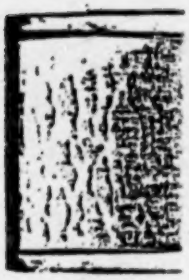
DATE RECEIVED ~~[illegible]~~ by [illegible]. SIGNATURE Shirley Larion SHOPPER

(Mail Delivery or Shopper Delivery) Jay Draper Witness

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center
3 - Low Income Residential Area
(4) - Middle Income Residential Area

PLAINTIFF'S EXHIBIT 97

Plaintiff's Exhibit 97



DONALD BOXMAN, D.O. - DIPLOMATE, AMERICAN OSTEOPATHIC BOARD OF GENERAL PRACTICE
AB 2726707

DAVID S. ROSENBERG, D.O.
AR 6133970

FARMINGTON CLINIC, P.C.
24300 ORCHARD LAKE ROAD
FARMINGTON, MICHIGAN 48024
TELEPHONE 474-5601

NAME Jay Draper AGE

ADDRESS DATE 4-21-78

℞ Cyclospasmol 400mg. #36
Sig: 1 bid

LABEL

Donald Boxman D.O.

NON-REF _____ REFILL _____ TIMES

Plaintiff's Exhibit 97

4/24/78	Boxman	510866	Drayer	440
DATE	DOCTOR	PRESCRIPTION NUMBER	PATIENT	AMOUNT

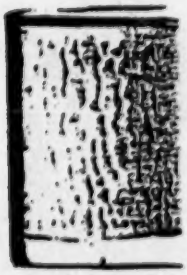
RETAIN THIS RECEIPT FOR PROOF OF MEDICAL EXPENSE

SENTRY DRUGS

Prescriptions

"Guards Your Health-Guards Your Dollars"

STORE NO.							
	1	2	3	4	5	6	7
	8	9	10	11	12	13	14
	15	16	17	18	19	20	



Plaintiff's Exhibit 97

SHOPPING REPORT

PHARMACY Sentry Prescrip. Drugs CITY Taylor

ADDRESS 22385 Ecorse Rd STATE Mich. ZIP 48180

*LOCATION: 1 __ 2 __ 3 __ 4 X 5 __ TYPE: SK __ K __ NK __

DATE: 4/24/78 TIME: 11:30 Am NO. CLERKS 2 NO. CUST. 3

DESCRIPTION OF PHARMACIST: DESCRIPTION OF CLERK:

M X F __ AGE 40 HAIR Black M- __ F x AGE 45 HAIR Gray

WEIGHT 175 lbs HEIGHT 5' 11" WEIGHT 140 lbs HEIGHT 5' 4"

GLASSES No MUSTACHE No GLASSES yes MUSTACHE —

OTHER CHARACTERISTICS long Sideburns OTHER CHARACTERISTICS —

TELEPHONE LOC. Behind counter USED BY PHARMACIST No

RX. DEPT. LOC. Back of store NO. OF R.PH. IN RX. DEPT. 2

I handed the Clerk-Pharmacist a prescription dated 4/21/78 made ou

to Jay Draper for Cyclospasmol 400 mg

by Doctor D. Boxman, D.O.

CONVERSATION:

SHOPPER - ~~[illegible]~~ Clerk asked address; insurance, etc.

~~[illegible]~~ - CLERK-R.PH.

SHOPPER - CLERK-R.PH.

I paid the clerk-pharmacist $ 4.40 and received a container containi

cyclandelate. The container bore a label with

the pharmacy name and address as above. Rx number 510866

Directions: One Capsule 2 times a Day

DOCTOR: D. Boxman, D.O. DATED: 4/24/78

I have identified the purchase by writing my name, the name and addre of the pharmacy, time, date and price of purchase ~~[illegible]~~ I sealed the container ~~[illegible]~~ in an envelope

DATE ~~[illegible]~~ Submitted.

REGISTERED NO.: _____

DATE RECEIVED ~~[illegible]~~ by [illegible] SIGNATURE [signature]

(Mail Delivery or Shopper Delivery) SHOPPER

---

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center
3 - Low Income Residential Area

PLAINTIFF'S EXHIBIT 97-A

Plaintiff's Exhibit 98

FARMINGTON MEDICAL CENTER, P. C.
OSTEOPATHIC PHYSICIANS AND SURGEONS
29538 ORCHARD LAKE ROAD AT 13 MILE ROAD
OFFICE PHONE MA 6-7544 FARMINGTON, MICHIGAN
OFFICE HOURS: MON. THRU FRI. 9:00-7:00. SAT. 9:00-2:00

ALBERT J. SCARCHILLI, D.O. AS-3056480
PAUL A. PARENTE, D.O. AP-2766561

FOR Jay Draper DATE 4/24/78

ADDRESS

℞ LABEL

Cyclopesmal 400mgm
#30

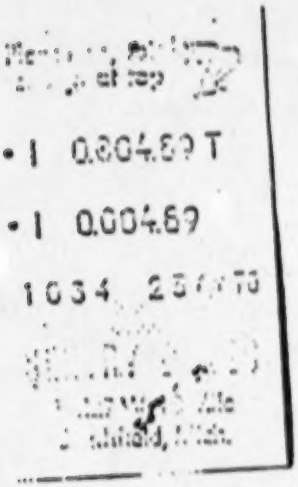
Sig ⊤ b.i.d

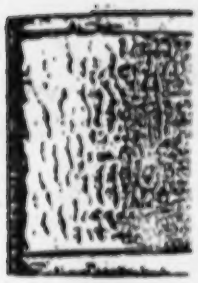
N. R. ☐
REFILL ____ TIMES

A J Scarchilli D.O.

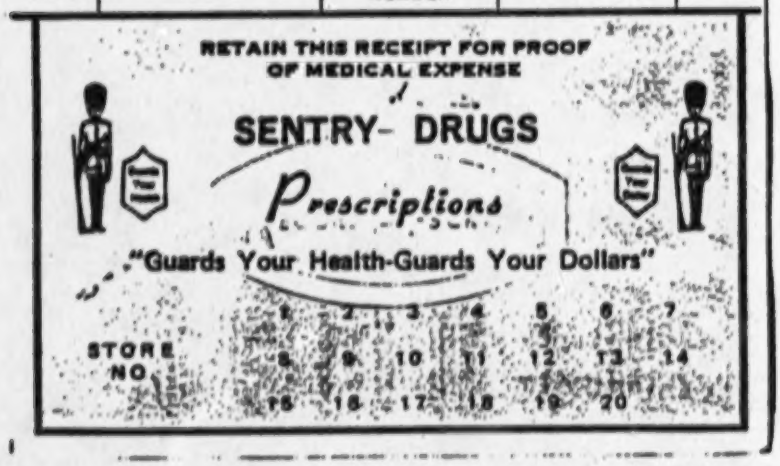
JOHN S. PHARMACY 31511 13 MILE NR ORCHARD LAKE RD. 353-3900

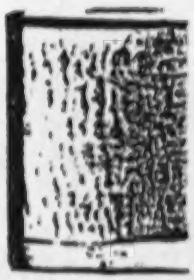
Plaintiff's Exhibit 98





4/25/78	Scarchilli	195313	Draper	489
DATE	DOCTOR	PRESCRIPTION NUMBER	PATIENT	AMOUNT





Plaintiff's Exhibit 98

SHOPPING REPORT

PHARMACY Sentry Drugs CITY South Field

ADDRESS 18227 W. 10 mile STATE Michigan ZIP 48075

*LOCATION: 1 __ 2 __ 3 __ 4 X 5 __ TYPE: SK __ K __ NK __

DATE: 4/25/78 TIME: 12:15 pm NO. CLERKS 1 NO. CUST. 4

DESCRIPTION OF PHARMACIST:

M X F __ AGE 28 HAIR Lt. Brown

WEIGHT 155 HEIGHT 5'11"

GLASSES No MUSTACHE yes

OTHER CHARACTERISTICS thin name was Jerry

DESCRIPTION OF CLERK:

M- __ F X AGE 19 HAIR Lt. Brown

WEIGHT 150 HEIGHT 5'3"

GLASSES No MUSTACHE —

OTHER CHARACTERISTICS none

TELEPHONE LOC. in Back USED BY PHARMACIST No

RX. DEPT. LOC. Back of store NO. OF R.PH. IN RX. DEPT. 1

I handed the Clerk-Pharmacist a prescription dated 4/24/78 made ou

to Jay Draper for Cyclospasmol 400 mg

by Doctor A. Scarchilli, D.O.

CONVERSATION:

SHOPPER - ~~[illegible]~~ clerk How to spell last name; address

~~[illegible]~~ - CLERK-R.PH.

SHOPPER - CLERK-R.PH. none

I paid the clerk-pharmacist $ 4.89 and received a container contain

cyclandelate 400 mg. The container bore a label wit

the pharmacy name and address as above. Rx number 195313

Directions: One capsule twice daily

DOCTOR: A. Scarchilli. DATED: 4/25/78

I have identified the purchase by writing my name, the name and addr of the pharmacy, time, date and price of purchase ~~[illegible]~~ ~~[illegible]~~. I sealed the container ~~[illegible]~~ in an envelope

DATE ~~[illegible]~~ submitted.

REGISTERED NO.: _____

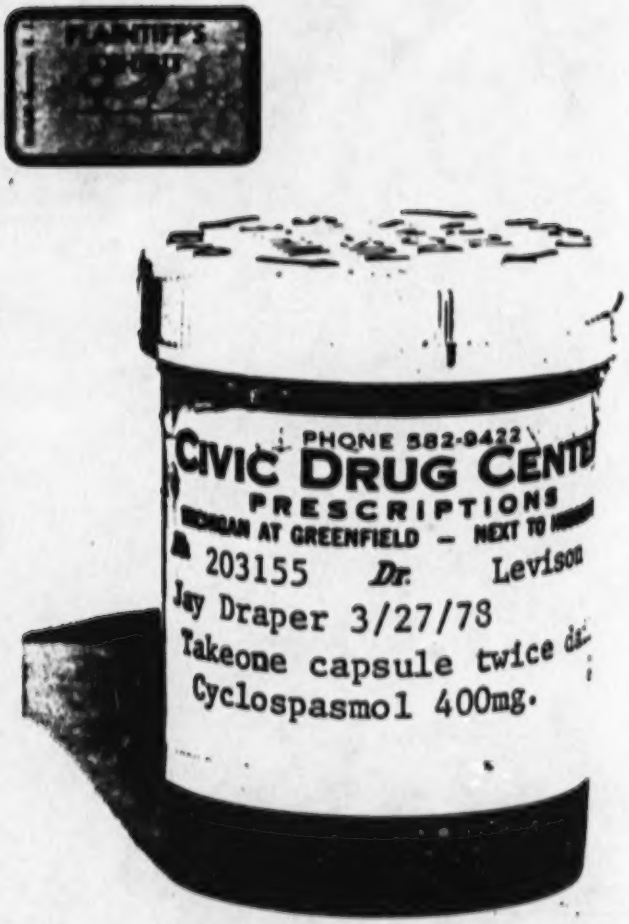
DATE RECEIVED ~~[illegible]~~ by [illegible] SIGNATURE [signature]

(Mail Delivery or Shopper Delivery)

PLAINTIFF'S EXHIBIT 78A

*Location: 1 - Downtown Business District

PLAINTIFF'S EXHIBIT 99



Plaintiff's Exhibit 99

ASSOCIATED INTERNISTS, P.C.
STANLEY H. LEVY, M.D., F.A.C.N.M.
DAVID M. JACOBS, M.D.
GERALD J. LEVINSON, D.O.-Cardiology
DIPLOMATES OF AMERICAN BOARD OF INTERNAL MEDICINE

10601 WEST SEVEN MILE ROAD
CORNER OF FINE HURST
DETROIT, MICHIGAN 48221
UNIVERSITY 1-7353
RESIDENCE
LINCOLN 7-0514

NAME Jerry Snyder

ADDRESS 7411 Shenandoah DATE 3/27/78

R

Cyclospasmol 400 mg #30

Sig: 1 b.i.d.

BNDD REG. NO.	MEDICAID NO.
AL 3069	1114329
AJ 2764	1114338
AL 3119	1167915

Gerald Levinson M.D.
LABEL PRODUCTS

Plaintiff's Exhibit 99

SHOPPING REPORT

PHARMACY CIVIC DRUG CENTER CITY DEARBORN

ADDRESS 15325 MICHIGAN AVE. STATE MICHIGAN ZIP 481 WAYNE COUNTY

*LOCATION: 1 __ 2 X 3 __ 4 __ 5 __ TYPE: SK __ K __ NK __

DATE: 3/27/78 TIME: 4:00 P.M. NO. CLERKS 5 NO. CUST. 6

DESCRIPTION OF PHARMACIST:

M X F __ AGE 30 HAIR SANDY

WEIGHT 169 HEIGHT 6'

GLASSES NO MUSTACHE X

OTHER CHARACTERISTICS AND BEARD

DESCRIPTION OF CLERK:

M- __ F X AGE 25 HAIR BLOND

WEIGHT 120 HEIGHT 5'3"

GLASSES NO MUSTACHE —

OTHER CHARACTERISTICS —

TELEPHONE LOC. BACK OF COUNTER USED BY PHARMACIST NO

RX. DEPT. LOC. BACK OF STORE NO. OF R.PH. IN RX. DEPT. 2

I handed the Clerk-Pharmacist a prescription dated 3/27/78 made ou

to JAY W. DRAPER for CYCLOSPASMOL 400 MG

by Doctor GERALD LEVINSON, D.O.

CONVERSATION:

SHOPPER - ~~[illegible]~~ PLEASE FILL THIS

~~[illegible]~~ - CLERK-R.PH. DO YOU HAVE INSURANCE?

SHOPPER - CLERK-R.PH. NO. I'LL PAY CASH (NOTHING ELSE SAID)

I paid the clerk-pharmacist $3.99 and received a container contain

30 CAPS. The container bore a label wit

the pharmacy name and address as above. Rx number 203155

Directions: TAKE ONE CAPSULE TWICE DAILY - CYCLOSPASMOL 400 MG.

DOCTOR: LEVINSON (PHARMACIST MISPELLED NAME "LEVISON") DATED: 3/27/78

I have identified the purchase by writing my name, the name and addr of the pharmacy, time, date and price of purchase ~~[illegible]~~ I sealed the container ~~[illegible]~~ in an envelope

DATE ~~[illegible]~~ Submitted.

REGISTERED NO.: _____

DATE RECEIVED ~~[illegible]~~ by [illegible] SIGNATURE [signature]

(Mail Delivery or Shopper Delivery)

SHOPPER

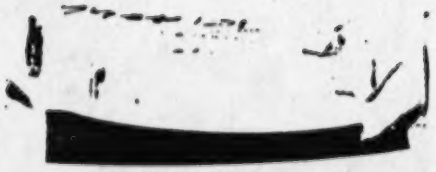
~~[illegible]~~ Jay Draper
23907 Pickett
Farmington, MI 48024
Phone: 313-477-2270

---

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center
3 - Low Income Residential Area
4 - Middle Income Residential Area

Witness [signature]

PLAINTIFF'S EXHIBIT 100



LOCUST 3-4860
LOCUST 3-4861

pickwick PHARMACY

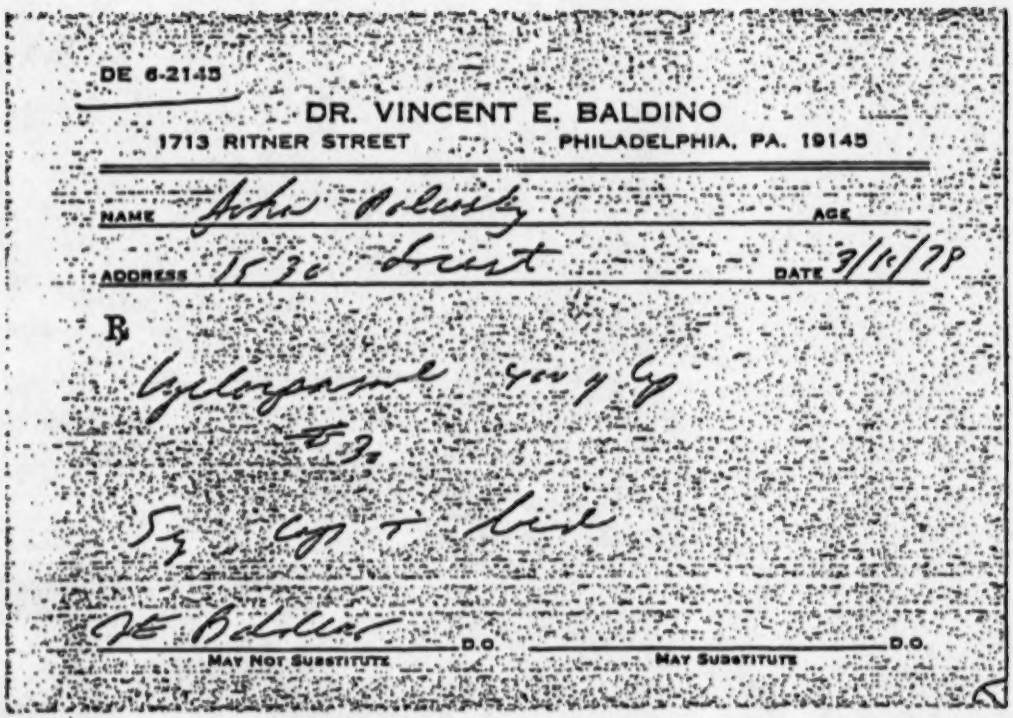
1700 MARKET ST., PHILA., PA. 19103

Jim Teasdale
94815 3-22-78 bk
One capsule three times a day. Br.Baldine $5.93/30
Cyclospasmol 400mgm

No. of refills 0 1 2 3 4 5 6 7 8 9

AP 4431932

Plaintiff's Exhibit 100



DE 6-2145

DR. VINCENT E. BALDINO

1713 RITNER STREET PHILADELPHIA, PA. 19145

NAME Asha Polesky AGE

ADDRESS 1530 Locust DATE 3/10/78

℞

Cyclospasmol 400 g Cap

#30

Sig. Cap + bid

VE Baldino D.O. D.O.

MAY NOT SUBSTITUTE MAY SUBSTITUTE

Plaintiff's Exhibit 100

RICKWICK PHARMACY
0643 T
0643
2 15 Mar 76
PA. 19103
LO 3-4860

RICKWICK PHARMACY
0643 T
0643
0431 25 Mar 76
PA. 19103
LO 3-4860

Rickwick PHARMACY
LOCUST 3-4860
LOCUST 3-4861
1700 MARKET ST., PHILA., PA. 19103

DATE	PHYSICIAN ORDERING PRESCRIPTION	REFILL NO.
3-22-76	Baldino	
NAME	Jim Teasdale	
ADDRESS		APT. NO.

TAKEN BY	FILLED BY	CASH	CHARGE	ON ACCT.	C.O.D.	WILL CALL	DELIVER

QTY	DESCRIPTION	PRICE	AMOUNT	
	94815		5	93
	Cyclospasmol			

PRESCRIPTIONS EXPERTLY COMPOUNDED. HAVE YOUR DOCTOR CALL US

Thank You

AMOUNT OF SALE		
TAX	$	
TOTAL	5	93

RECEIVED BY

Plaintiff's Exhibit 100

SHOPPING REPORT

PHARMACY Pickwick Phcy. CITY Phila.

ADDRESS 1700 Market St. STATE Pa. ZIP 19103

*LOCATION: (1) 2 3 4 5 TYPE: SK K NK

DATE: 3-22-78 TIME: 10:35 AM NO. CLERKS 2 NO. CUST. 0

DESCRIPTION OF PHARMACIST: DESCRIPTION OF CLERK: Same Fees

M F ✓ AGE 25-30 yr HAIR Brown M F AGE HAIR

WEIGHT 90-100 lbs HEIGHT 5'-5'2" WEIGHT HEIGHT

GLASSES Large MUSTACHE GLASSES MUSTACHE

OTHER CHARACTERISTICS Longish hair olive complexion OTHER CHARACTERISTICS

TELEPHONE LOC. Do not recall USED BY PHARMACIST

RX. DEPT. LOC. Behind Front Counter NO. OF R.PH. IN RX. DEPT. 2

I handed the Clerk-Pharmacist a prescription dated 3-15-78 made o

to Jim Teasdale for 30 Cyclospasmol Caps 400 mg

by Doctor Vincent Baldino DO.

CONVERSATION:

SHOPPER - ~~[illegible]~~ I would like this Rx filled I will wait

~~[illegible]~~ - CLERK-R.PH. OK

SHOPPER - CLERK-R.PH.

I paid the clerk-pharmacist $ 5.93 and received a container contain

. The container bore a label wit

the pharmacy name and address as above. Rx number 94815

Directions: 1 B.I.D.

DOCTOR: Vincent Baldino D.O. DATED: 3-15-78

I have identified the purchase by writing my name, the name and addr of the pharmacy, time, date and price of purchase ~~[illegible]~~ 15 ~~[illegible]~~. I sealed the container ~~[illegible]~~ in an envelope

DATE ~~[illegible]~~ Submitted.

REGISTERED NO.:

DATE RECEIVED ~~[illegible]~~ by [illegible] SIGNATURE [signature]

(Mail Delivery or Shopper Delivery) SHOPPER

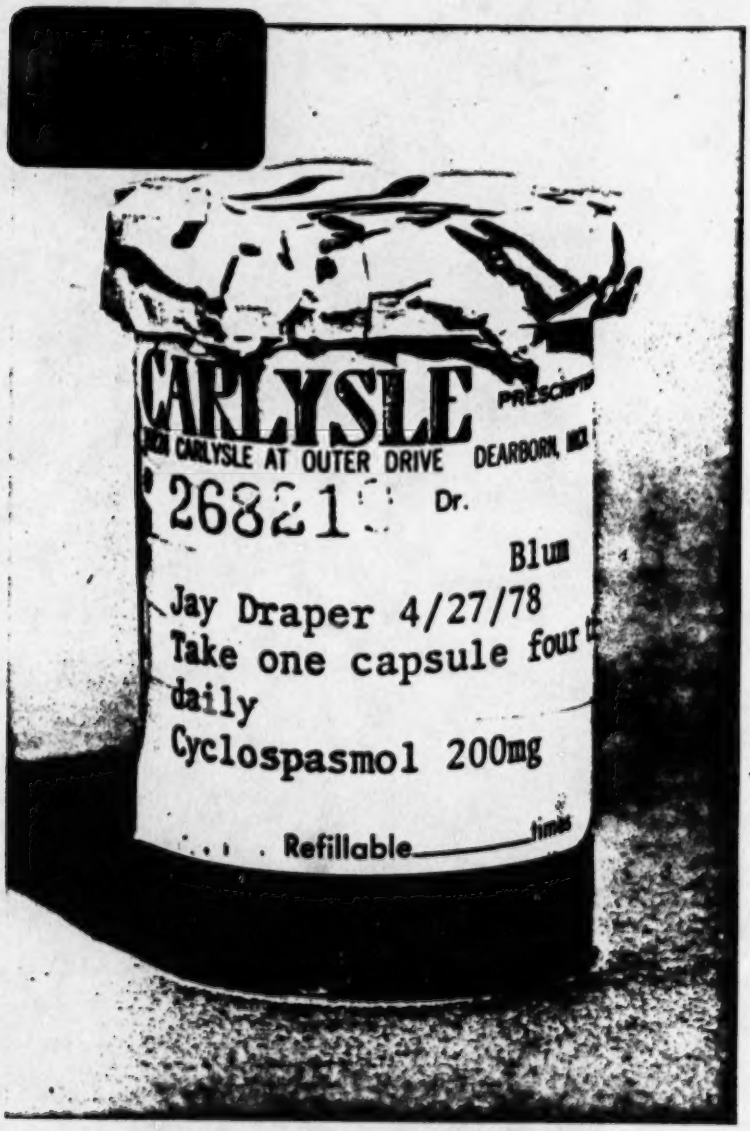
RECEIVED
APR 12 1978
STEVEN J. BARON

PLAINTIFF'S EXHIBIT 100A

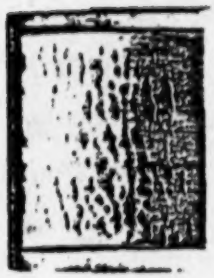
---

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center
3 - Low Income Residential Area
4 - Middle Income Residential Area

PLAINTIFF'S EXHIBIT 101



Plaintiff's Exhibit 101



DR. DAVID BLUM

DETROIT 35, MICHIGAN

Office Hours Daily, Except Thurs.
By Appointment Only

NAME Jay Klapper AGE

ADDRESS DATE 4-27-78

℞ Cyclospasmol 200 mg

#60

Sig: 1 Cap qid.

AB3047/58

____NON-REPETATUR
____REPETATUR SEMEL
____REPETATUR BIS.
____REPETATUR EX PRAECEPTO

Reg. No. 10182 David Blum DPM. L.S.C.

Plaintiff's Exhibit 101

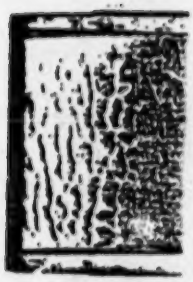
THANK YOU

A 0.007.69 T 2

2 0.007.69 2

2010 24 Feb 76

CALL AGAIN



DATE	DOCTOR	R.P.	REFILL TIMES	PRESCRIPTION NUMBER	PATIENT	AMOUNT
4.27.8	BLUM			268210	JAM DRAPER	769

RETAIN THIS RECEIPT FOR PROOF OF MEDICAL EXPENSE

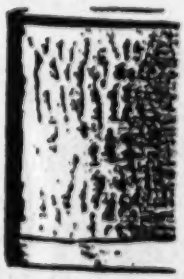
CARLYSLE PHARMACY

19224 CARLYSLE AT OUTER DRIVE ; DEARBORN, MICH.

PHONE LO 1-6100

"Shop - Save - Smile - at Carlysle"

YOU CAN ALWAYS CHECK YOUR PRESCRIPTION PURCHASES AT THIS STORE



PLAINTIFF'S EXHIBIT 101

Plaintiff's Exhibit 101

SHOPPING REPORT

PHARMACY Carlysle Prescriptions CITY Dearborn

ADDRESS 19224 Carlysle STATE Michigan ZIP 48124

*LOCATION: 1 ___ 2 ___ 3 ___ 4 X 5 ___ TYPE: SK ___ K ___ NK ___

DATE: 4/27/78 TIME: 11:30 NO. CLERKS 1 NO. CUST. 3

DESCRIPTION OF PHARMACIST:

M X F ___ AGE 27 HAIR Black

WEIGHT 160 HEIGHT 5'10"

GLASSES no MUSTACHE yes

OTHER CHARACTERISTICS ___

DESCRIPTION OF CLERK:

M- ___ F X AGE 19 HAIR Black

WEIGHT 115 HEIGHT 5'4"

GLASSES no MUSTACHE —

OTHER CHARACTERISTICS —

TELEPHONE LOC. Behind Counter USED BY PHARMACIST No

RX. DEPT. LOC. Back of store NO. OF R.PH. IN RX. DEPT. 1

I handed the Clerk-Pharmacist a prescription dated 4/27/78 made out to Jay Draper for Cyclospasmol 200 mg caps by Doctor David Blum (D.P.M.).

CONVERSATION:

SHOPPER - ~~[illegible]~~ Asked about Insurance, address

~~[illegible]~~ - CLERK-R.PH. —

SHOPPER - CLERK-R.PH. no

I paid the clerk-pharmacist $7.69 and received a container containi: Cyclandelate 200 mg. The container bore a label with the pharmacy name and address as above. Rx number 268210

Directions: One capsule 4 times daily

DOCTOR: David Blum. DATED: 4/27/78

I have identified the purchase by writing my name, the name and addre of the pharmacy, time, date and price of purchase ~~[illegible]~~. I sealed the container ~~[illegible]~~ in an envelope

DATE ~~[illegible]~~ Submitted.

REGISTERED NO.: ___

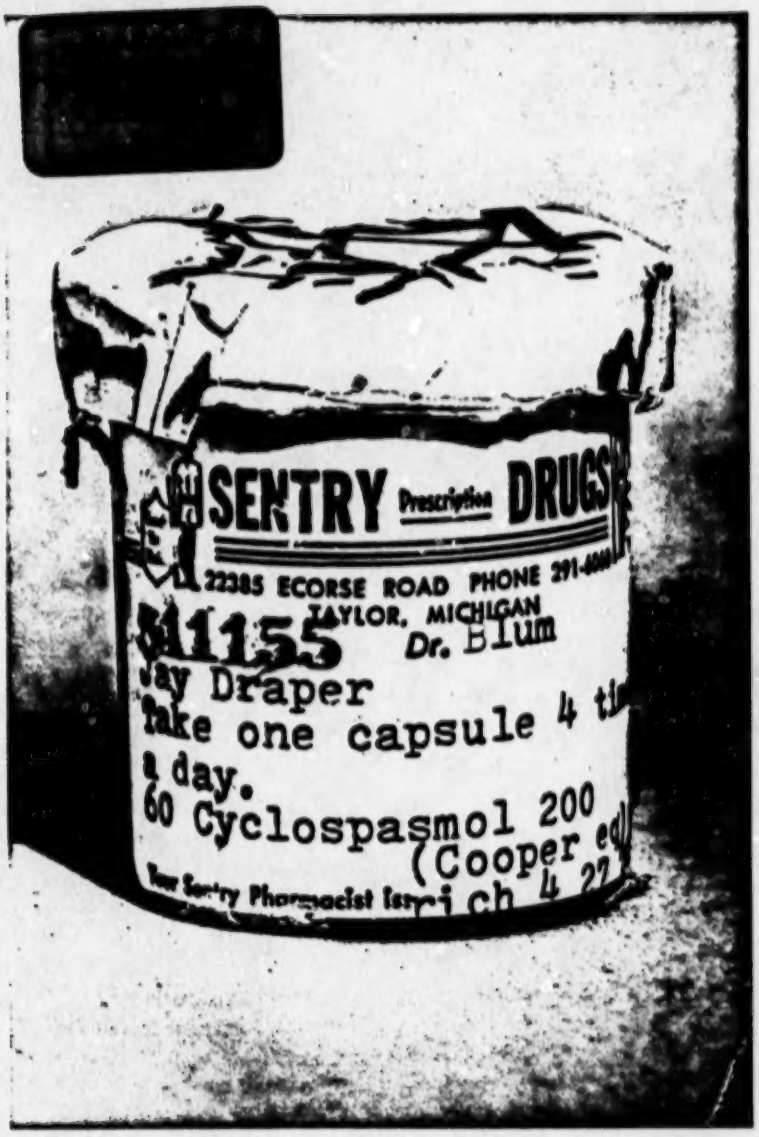
DATE RECEIVED ~~[illegible]~~ by [illegible]. SIGNATURE [signature]

(Mail Delivery or Shopper Delivery) SHOPPER

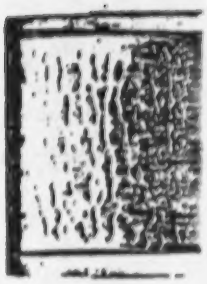
---

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center

PLAINTIFF'S EXHIBIT 102



Plaintiff's Exhibit 102



DR. DAVID BLUM
Foot Specialist and Ray Physiotherapy
15311 WEST McNICHOLS AVE.
DETROIT 35, MICHIGAN

Phone 272-4884

Office Hours: Daily, Except Thurs. By Appointment Only

NAME Jay Draper AGE

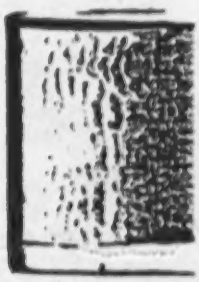
ADDRESS DATE 4-27-78

℞ Cyclospasmol 200 mg
#60
Sig: T cap. q.i.d.

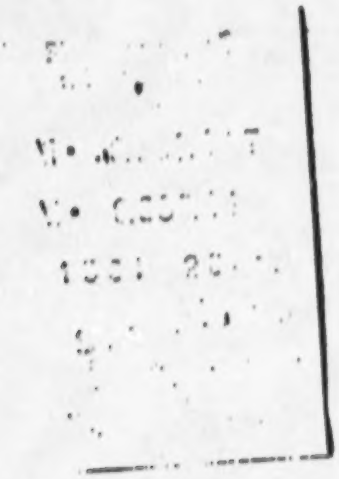
BNDD REGISTRATION NUMBER
AB3047758

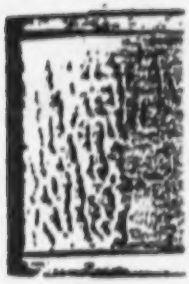
___NON-REPETATUR
___REPETATUR SEMEL
___REPETATUR BIS.
___REPETATUR EX PRAECEPTO

REG. No. 10182 David Blum DPM D.S.C.



Plaintiff's Exhibit 102





DATE	DOCTOR	PRESCRIPTION NUMBER	PATIENT	AMOUNT
9/27/78	Blum	511155	Draper	5.65

RETAIN THIS RECEIPT FOR PROOF OF MEDICAL EXPENSE

SENTRY DRUGS

Prescriptions

"Guards Your Health-Guards Your Dollars"

STORE NO.

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	

Plaintiff's Exhibit 102

SHOPPING REPORT

PHARMACY Sentry Pres. Drugs CITY Taylor

ADDRESS 22385 Ecorse Rd. STATE Michigan ZIP 48180

*LOCATION: 1__ 2__ 3__ 4 X 5__ TYPE: SK__ K__ NK__

DATE: 4/27/78 TIME: 12:00 Pm NO. CLERKS 2 NO. CUST. 6

DESCRIPTION OF PHARMACIST:		DESCRIPTION OF CLERK:	
M X F__		M__ F X	
AGE	35	AGE	55
HAIR	Black	HAIR	GRAY
WEIGHT	200	WEIGHT	145
HEIGHT	6'1"	HEIGHT	5'5"
GLASSES	no	GLASSES	no
MUSTACHE	no	MUSTACHE	—
OTHER CHARACTERISTICS	long Sideburns	OTHER CHARACTERISTICS	—

TELEPHONE LOC. In Behind Counter USED BY PHARMACIST No

RX. DEPT. LOC. IN BACK NO. OF R.PH. IN RX. DEPT. 1

I handed the Clerk-Pharmacist a prescription dated 4/27/78 made out to Jay Draper for Cyclospasmol 200 mg by Doctor David Blum, D.P.M.

CONVERSATION:

SHOPPER - [redacted] insurance, spelling of name

[redacted] - CLERK-R.PH. None

SHOPPER - CLERK-R.PH. None

I paid the clerk-pharmacist $ 5.65 and received a container containing Cyclandelate. The container bore a label with the pharmacy name and address as above. Rx number 511155

Directions: One Capsule 4 times a Day

DOCTOR: David Blum. DATED: 4/27/78

I have identified the purchase by writing my name, the name and address of the pharmacy, time, date and price of purchase [redacted] I sealed the container [redacted] in an envelope

DATE [redacted] Submitted.

REGISTERED NO.: _____

DATE RECEIVED [redacted] by Mail. SIGNATURE _____ SHOPPER

(Mail Delivery or Shopper Delivery)

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center

PLAINTIFF'S EXHIBIT 103

Plaintiff's Exhibit 103

HARVEY YALE SAKOFSKY, M.D.
338 EAST 30TH STREET
NEW YORK, N.Y. 10016
212—684-3410

DEA NO. AS 7013117

DATE 12/16/77

NAME K Budz

℞

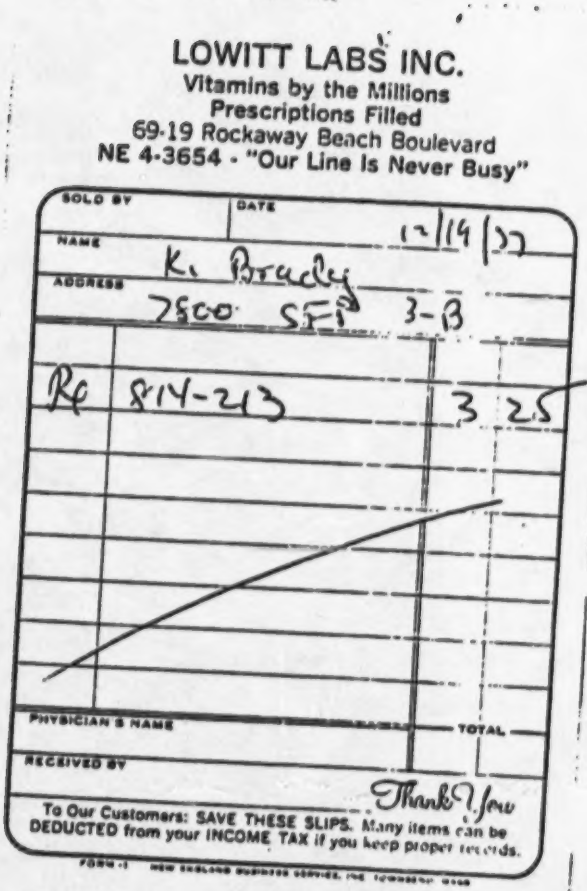
Cyclosporin Capsules (200mg)

Sig: i.s.i.d.
Disp #60

☐ REFILL 4 TIMES
☐ NON REPETATUR

Harvey Y. Sakofsky M.D.

Plaintiff's Exhibit 103



LOWITT LABS INC.
Vitamins by the Millions
Prescriptions Filled
69-19 Rockaway Beach Boulevard
NE 4-3654 - "Our Line Is Never Busy"

SOLD BY
DATE 12/14/32
NAME K. Bracky
ADDRESS 7500 SFI 3-B
Rx 814-213 3 25
PHYSICIAN'S NAME
TOTAL
RECEIVED BY
Thank You
To Our Customers: SAVE THESE SLIPS. Many items can be DEDUCTED from your INCOME TAX if you keep proper records.
FORM 1 NEW ENGLAND BUSINESS SERVICE, INC. NEWTON, MASS.

Plaintiff's Exhibit 103

SHOPPING REPORT

PHARMACY Lovett Labs CITY _____

ADDRESS 69-19 Kissena Blvd. Flushing STATE _____ ZIP _____

*LOCATION: 1__ 2__ 3✓ 4__ 5__ TYPE: SK__ K__ NK__

DATE: 12/19/77 TIME: 11:40 AM NO. CLERKS ____ NO. CUST. ____

DESCRIPTION OF PHARMACIST:

M ✓ F__ AGE 30's HAIR Brown

WEIGHT 160 HEIGHT 5'6"

GLASSES ____ MUSTACHE ✓

OTHER CHARACTERISTICS beard

DESCRIPTION OF CLERK:

M__ F__ AGE____ HAIR ____

WEIGHT ____ HEIGHT ____

GLASSES ____ MUSTACHE ____

OTHER CHARACTERISTICS ____

TELEPHONE LOC. Rt. hand side behind pharmacy counter USED BY PHARMACIST No

RX. DEPT. LOC. left of door NO. OF ~~R.PH.~~ PHARMACISTS IN RX. DEPT. 3

I handed the ~~Clerk-Pharmacist~~ a prescription dated 12-16-77 made out to K. Brady for Cyclospasmol 200 mg.

by Doctor _____.

CONVERSATION:

SHOPPER - ~~CLERK-R.PH.~~ I'd like to fill this prescription for my father

~~SHOPPER - CLERK~~ - R.PH. Brady? What's the address?

SHOPPER - ~~CLERK-R.PH.~~ yes 7800 Main Front Parkway Apt. 3B

I paid the clerk-pharmacist $3.35 and received a container containing _____. The container bore a label with the pharmacy name and address as above. Rx number 814-213.

Directions: _____.

DOCTOR: _____. DATED: _____.

I have identified the purchase by writing my name, the name and address of the pharmacy, time, date and price of purchase on a label, affixing the same to the container. I sealed the container with a seal bearing my initials.

PLAINTIFF'S EXHIBIT 54

DATE MAILED TO CHEMIST: _____

REGISTERED NO.: _____

DATE RECEIVED BY CHEMIST: _____. SIGNATURE _____ SHOPPER

(Mail Delivery or Shopper Delivery)

*Location: 1 - Downtown Business District

2 - Suburban Shopping Center

Plaintiff's Exhibit 103

SEYMOUR ADLER
Confidential Investigations
PATENT INFRINGEMENT • PRIOR ART
TRADE MARK • COPYRIGHT
UNFAIR COMPETITION
MARKET SURVEYS
LIC. & BONDED BY STATE OF N. Y.

2300 OLINVILLE AVENUE
NEW YORK, N. Y. 10467
—
DAY 212 682-6770
NITE 212 OL 5-6202

Subject: Lowitt Labs.
69-19 Rockaway Beach Boulevard
Arverne, N.Y.

Date: Jan. 25, 1978 11:20 AM

Report by: Seymour Adler

Des. of Clerk: Male, age 27, 160 lbs, brown hair and beard.

Entered this store, and told the above described clerk that I would like a refill for prescription number 814-213, for K. Brady, 7800 Shore Front Parkway, Dr. Sakofsky.

The clerk went to rear of store, checked his files, and returned shortly with a filled prescription. He handed me a filled prescription, and said that the price would be $3.25. The writer paid the clerk $3.25.

The prescription bore the drug store label, and also bore the following:-

RX 814-213, date 12/19/77, K. Brady, 7800 SFP, 1 capsule 4 times daily.

No. 60 Cyclospasmol, 200 mg. F, Dr. Sakofsky.

Prescription was identified by affixing a label on to it with the following information:- Name and address of store, time, date, price paid, RX number, and signature of shopper.

Seymour Adler

Plaintiff's Exhibit 103

LOWITT LABS INC.
Vitamins by the Millions
Prescriptions Filled
69-19 Rockaway Beach Boulevard
NE 4-3654 - "Our Line Is Never Busy"

SOLD BY | DATE 1/25/28

NAME K. Brady

ADDRESS 7800 SFP.

Rp	814-43	3 25

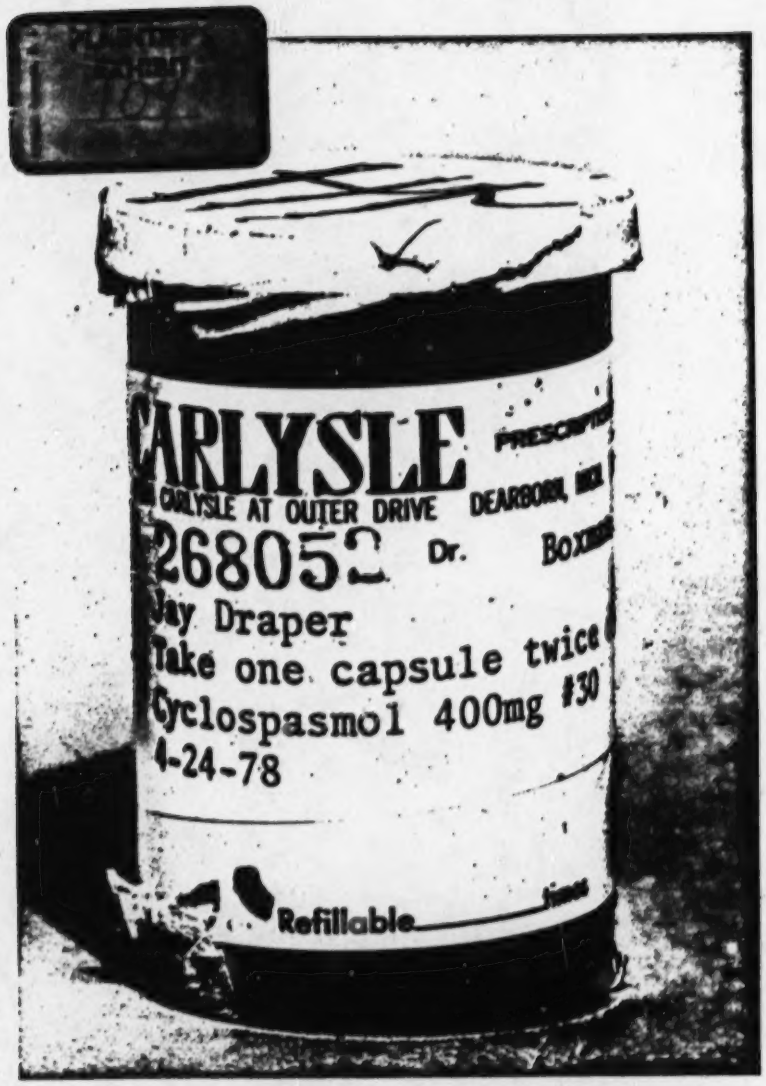
PHYSICIAN'S NAME — TOTAL

RECEIVED BY — Thank You

To Our Customers: SAVE THESE SLIPS. Many items can be DEDUCTED from your INCOME TAX if you keep proper records.

FORM 1 NEW ENGLAND BUSINESS SERVICE, INC. YONKERS, MASS.

PLAINTIFF'S EXHIBIT 104



Plaintiff's Exhibit 104

DONALD BOXMAN, D.O. - DIPLOMATE, AMERICAN OSTEOPATHIC BOARD OF GENERAL PRACTICE
AB 2726707

DAVID S. ROSENBERG, D.O.
AR 6133970

FARMINGTON CLINIC, P.C.
24300 ORCHARD LAKE ROAD
FARMINGTON, MICHIGAN 48024
TELEPHONE 474-5601

NAME Jay Draper AGE

ADDRESS DATE 4-21-72

℞

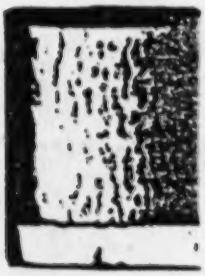
Cyclospasmol 400mg #30

Sig: ÷ bid

LABEL

Donald Boxman D.O.

NON-REF. REFILL TIMES



Plaintiff's Exhibit 104

DATE	DOCTOR	R.PH.	REFILL TIMES	PRESCRIPTION NUMBER	PATIENT	AMOUNT
4/24/18	Bosman			26805	Jay Draper	599

RETAIN THIS RECEIPT FOR PROOF OF MEDICAL EXPENSE

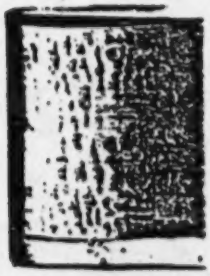
CARLYSLE PHARMACY

19224 CARLYSLE AT OUTER DRIVE DEARBORN, MICH.

PHONE LO 1-6100

"Shop - Save - Smile - at Carlysle" 230

YOU CAN ALWAYS CHECK YOUR PRESCRIPTION PURCHASES AT THIS STORE



Plaintiff's Exhibit 104

SHOPPING REPORT

PHARMACY Carlysle Prescrip. CITY Dearborn, Mich.

ADDRESS 19224 Carlysle STATE Michigan ZIP 48124

*LOCATION: 1 2 3 4 X 5 TYPE: SK K NK

DATE: 4/24/78 TIME: 10:45 AM NO. CLERKS 1 NO. CUST. 3

DESCRIPTION OF PHARMACIST:

M X F AGE 28 HAIR Blond

WEIGHT 148 lbs HEIGHT 5'9"

GLASSES No MUSTACHE X

OTHER CHARACTERISTICS —

DESCRIPTION OF CLERK:

M- F X AGE 55 HAIR Gray

WEIGHT 130 HEIGHT 5'4"

GLASSES yes MUSTACHE

OTHER CHARACTERISTICS —

TELEPHONE LOC. Behind Counter USED BY PHARMACIST No

RX. DEPT. LOC. Back NO. OF R.PH. IN RX. DEPT. 1

I handed the Clerk-Pharmacist a prescription dated 4/21/78 made ou

to Jay Draper for Cyclospasmol 400 mg

by Doctor Donald Boxman, D.O.

CONVERSATION:

SHOPPER - ~~[illegible]~~ clerk ASKED Age, cash payment, et

~~[illegible]~~ - CLERK-R.PH.

SHOPPER - CLERK-R.PH.

I paid the clerk-pharmacist $5.99 and received a container containi

30 caps, cyclandelate. The container bore a label with

the pharmacy name and address as above. Rx number 268052

Directions: One capsule twice daily

DOCTOR: Boxman. DATED: 4/24/78

I have identified the purchase by writing my name, the name and addr

of the pharmacy, time, date and price of purchase ~~[illegible]~~ I sealed the container ~~[illegible]~~ in an envelope

DATE ~~[illegible]~~ submitted.

REGISTERED NO.:

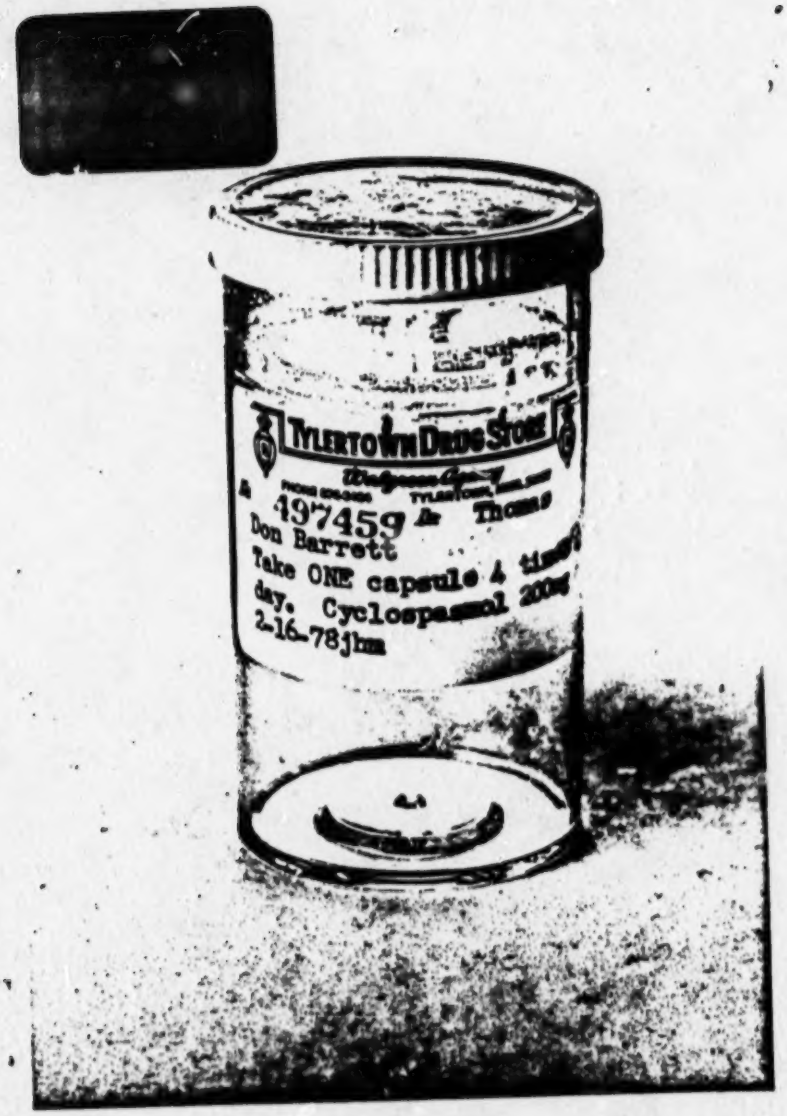
DATE RECEIVED ~~[illegible]~~ by [illegible]. SIGNATURE [signature]

(Mail Delivery or Shopper Delivery) SHOPPER

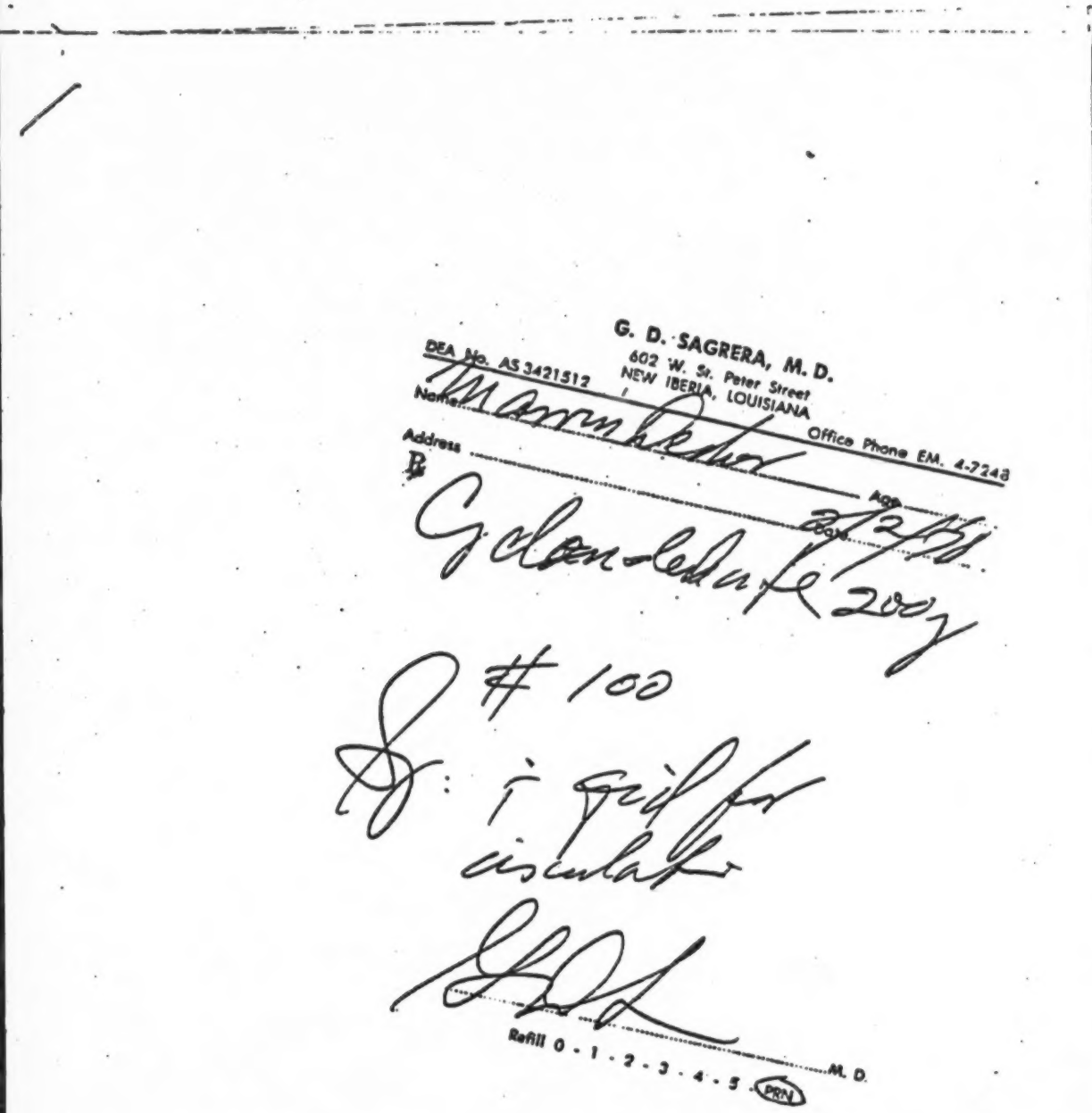
PLAINTIFF'S EXHIBIT [illegible]

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center
3 - Low Income Residential Area
4 - Middle Income Residential Area

PLAINTIFF'S EXHIBIT 105



Plaintiff's Exhibit 105



Plaintiff's Exhibit 105

RECORD FOR MEDICINE

SAVE FOR YOUR INCOME TAX DEDUCTIONS

DATE 197

We appreciate the opportunity of filling your prescription. It is filled with the best obtainable standardized ingredients.

NIGHT & SUNDAY PHONE 876-5938

FOR

NO. 497460 $ 9.85

NO. $

NO. $

NO. $

TOTAL $

TYLERTOWN DRUG STORE

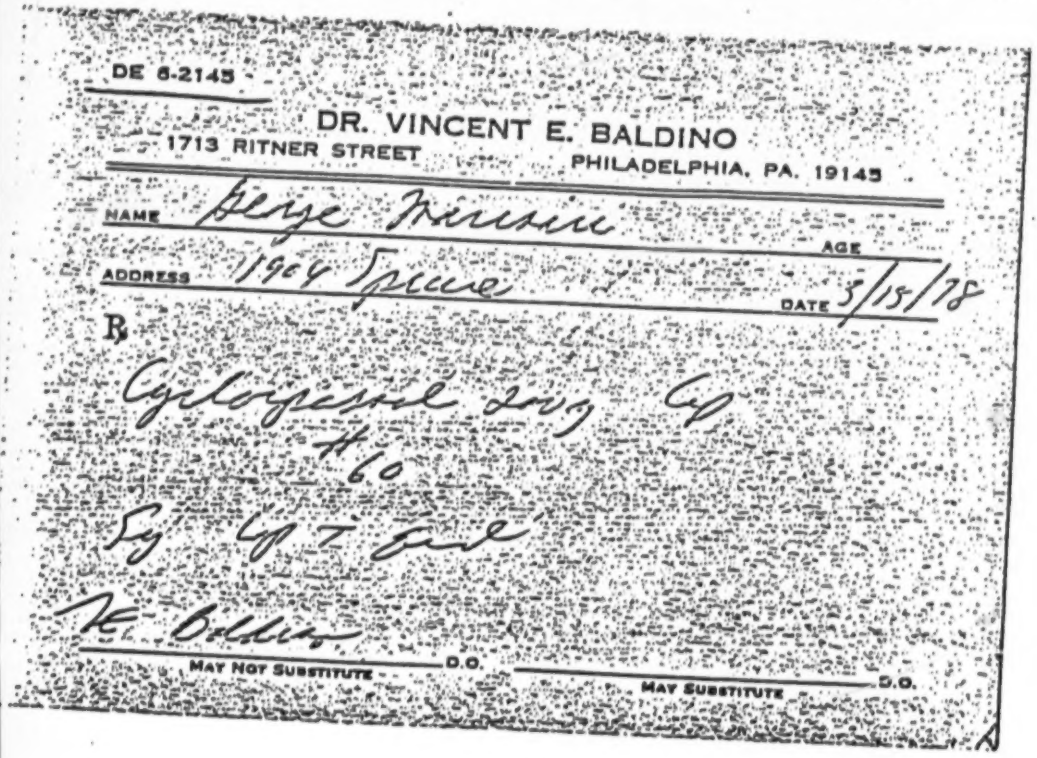
Phone 876-3424

Tylertown, Mississippi

PLAINTIFF'S EXHIBIT

PLAINTIFF'S EXHIBIT 106

Plaintiff's Exhibit 106



DE 6-2145

DR. VINCENT E. BALDINO

1713 RITNER STREET PHILADELPHIA, PA. 19145

NAME George Mansini AGE

ADDRESS 1904 Spruce DATE 5/15/78

℞

Cyclopentol 2oz Cp

#60

Sig Cp T Qid

VE Baldino

MAY NOT SUBSTITUTE D.O. MAY SUBSTITUTE D.O.

Plaintiff's Exhibit 106

SHOPPING REPORT

PHARMACY Pickwick Phcy CITY Phila

ADDRESS 1700 Market St STATE Pa ZIP

*LOCATION: (1) 2 3 4 5 TYPE: SK K NK

DATE: MAR 15, 78 TIME: 2:20PM NO. CLERKS 2 NO. CUST. 1

DESCRIPTION OF PHARMACIST: (M) F AGE 28 HAIR

WEIGHT 150 HEIGHT 5'8"

(GLASSES) MUSTACHE

OTHER CHARACTERISTICS curly hair

DESCRIPTION OF CLERK: M F AGE HAIR

WEIGHT HEIGHT

(GLASSES) MUSTACHE

OTHER CHARACTERISTICS

TELEPHONE LOC. behind counter USED BY PHARMACIST

RX. DEPT. LOC. rear of store NO. OF R.PH. IN RX. DEPT. 2

I handed the Clerk-Pharmacist a prescription dated March 15, 78 made out to George Marinari for

by Doctor Baldino, DO.

CONVERSATION:

SHOPPER - ~~CLERK-R.PH.~~ none

~~SHOPPER~~ - CLERK-R.PH. hear is your Rx.

SHOPPER - CLERK-R.PH.

I paid the clerk-pharmacist $ ~~[illegible]~~ 6.43/60 and received a container containin blue unmarked capsules. The container bore a label with the pharmacy name and address as above. Rx number 94616.

Directions: one capsule 4X day

DOCTOR: Baldino. DATED: Mar 15, 78

I have identified the purchase by writing my name, the name and addres of the pharmacy, time, date and price of purchase ~~[illegible]~~. I sealed the container ~~with [illegible]~~ in an envelope

DATE ~~[illegible]~~ Submitted.

REGISTERED NO.:

DATE RECEIVED ~~[illegible]~~ by [illegible]. SIGNATURE George Marinari

(Mail Delivery or Shopper Delivery) SHOPPER

PLAINTIFF'S EXHIBIT [illegible]

RECEIVED APR 12 1978 STEVEN I. BARON

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center

PLAINTIFF'S EXHIBIT 107

Plaintiff's Exhibit 107

SHOPPING REPORT

PHARMACY Pickwick Phcy CITY Phila

ADDRESS 1700 market St STATE Pa ZIP _____

*LOCATION: (1) 2 3 4 5 TYPE: SK ___ K ___ NK ___

DATE: March 27, TIME: 11:30 AM NO. CLERKS 2 NO. CUST. 1

DESCRIPTION OF PHARMACIST:	DESCRIPTION OF CLERK:
M (F) AGE 28 HAIR _____	M ___ F ___ AGE _____ HAIR _____
WEIGHT 125 HEIGHT 5'2"	WEIGHT _____ HEIGHT _____
(GLASSES) _____ MUSTACHE _____	GLASSES _____ MUSTACHE _____
OTHER CHARACTERISTICS dark hair	OTHER CHARACTERISTICS _____

TELEPHONE LOC. behind counter USED BY PHARMACIST no

RX. DEPT. LOC. rear of store NO. OF R.PH. IN RX. DEPT. 2

I handed the Clerk-Pharmacist a prescription dated _____ made out to _____ for _____

by Doctor _____

CONVERSATION:

SHOPPER - [redacted] I don't have my bottle but the number is 94616

[redacted] - CLERK-R.PH. yes is your name Marmere

SHOPPER - CLERK-R.PH. yes

I paid the clerk-pharmacist $6.43 and received a container containi half blue caps marked Tues and half blue caps with no markings. The container bore a label with the pharmacy name and address as above. Rx number _____

Directions: One cap 4X day

DOCTOR: Baldeon . DATED: March 27, 78

I have identified the purchase by writing my name, the name and addre of the pharmacy, time, date and price of purchase on the [redacted] I sealed the container with the [redacted] in an envelope

DATE [redacted] March 27.

REGISTERED NO.: _____

DATE RECEIVED [redacted] by Mail. SIGNATURE Nancy Marmere SHOPPER

(Mail Delivery or Shopper Delivery)

PLAINTIFF'S EXHIBIT [illegible]

RECEIVED

APR 12 1978

STEVEN J. BARON

*Location: 1 - Downtown Business District
2 - Suburban Shopping Center
3 - Low Income Residential Area
4 - Middle Income Residential Area

PLAINTIFF'S EXHIBIT 112

United States Patent Office

602,919
Registered Mar. 8, 1955

AFFIDAVIT SEC. 8
ACCEPTED

PRINCIPAL REGISTER
Trade-Mark

AFFIDAVIT SEC 15
RECEIVED 12-2-60

Ser. No. 641,212, filed Feb. 17, 1954

CYCLOSPASMOL

N. V. Koninklijke Pharmaceutische Fabrieken v/h Brocades-Stheeman & Pharmacia (Dutch corporation)
Leeuwenbrug, Amsterdam, Netherlands

For: PHARMACEUTICAL SPASMOLYTIC PREPARATION WITH VASODILATING PROPERTIES, in CLASS 18.
First used on or about Nov. 26, 1951, and in commerce on or about Nov. 26, 1951.
Owner of Reg. No. 525,102.

Renewed for 20 years from Mar. 8, 1975

COMB. AFF. SEC 8 & 15

Attest:

OCT 14 1977

Attesting Officer

CERTIFIED TO BE A TRUE COPY OF THE REGISTRATION WHICH IS IN FULL FORCE AND EFFECT, WITH NOTATION OF ALL STATUTORY ACTIONS TAKEN THEREON, AS DISCLOSED BY THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE. SAID RECORDS SHOW TITLE TO BE IN: Ives Laboratories Inc., a N.Y. corp.

ACTING COMMISSIONER OF PATENTS & TRADEMARKS

EXHIBIT C

LEGEND

PDR - refers to the Physicians Desk Reference

* - identifies page number of "Product Identification" Section of PDR

** - identifies page number of "Product Information" Section of PDR

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
6. Hydralazine Hydrochloride	Apresoline	blue round tablet (25mg)	Ciba Pharmaceutical	12*	408*
Hydralazine Hydrochloride	Dralzine	yellow oblong tablet (25mg)	Lemmon Pharmaceutical Co.	925**	984**
16. Dicyclomine Hydrochloride	Bentyl	blue capsule (10mg)	Merrell-National	22*	419*
Dicyclomine Hydrochloride	Bentyl	blue tablet (20mg)	Merrell-National	22*	419*
Dicyclomine Hydrochloride	Dyspas	green tablet (10mg)	Savage Laboratories	1382**	-
Dicyclomine Hydrochloride	Dyspas	yellow tablet (20mg)	Savage Laboratories	1382**	-
17. Cyclandelate	Cyclospasmol	pale blue capsule (200mg)	Ives Laboratories	15*	412*
Cyclandelate	Cyclanfor	lime capsule (200mg)	Forest Laboratories	Plaintiff's Exhibit L-X	-
Cyclandelate	Cydel	red capsule (200 mg)	W.E. Hauck	Plaintiff's Exhibit L-W	-

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
18. Cyclandelate	Cyclospasmol	pale blue/red capsule	Ives Laboratories	15*	41**
Cyclandelate	Cyclanfor	green capsule(400 mg)	Forest Laboratories	Plaintiff's Exhibit 1.	
19. Dexamethasone	Decadron	blue pentagonal tablet (0.75mg)	Merck Sharp & Dohme	21*	11**
Dexamethasone	Deronil	amber oval tablet (0.75 mg)	Schering	33*	430*
21. 12mg Brompheniramine Maleate 15mg Phenylephrine Hydrochloride 15mg Phenylpropanolamine Hydrochloride	Dimetapp Extentabs	blue round tablet	A.H. Robins	28*	425*
12mg Brompheniramine Maleate 12mg Phenylephrine Hydrochloride 15mg Phenylpropanolamine Hydrochloride	Drocon	pink round tablet	Forest Laboratories	827** Field deposition page 77	-
27. Amitriptyline Hydrochloride	Elavil	blue round tablet (10mg)	Merck Sharp & Dohme	21*	419*
Amitriptyline Hydrochloride	Endep	orange round tablet (10 mg)	Roche	30*	426*
Amitriptyline Hydrochloride	Amitril	tan round tablet 10 mg)	Warner/Chilcott	-	438* 1809**

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	Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
28.	Amitriptyline Hydrochloride	Elavil	yellow round tablet (25 mg)	Merck Sharp & Dohme	21*	416* 426*
	Amitriptyline Hydrochloride	Endep	orange round tablet (25 mg)	Roche	30*	434*
	Amitriptyline Hydrochloride	Amitril	coral tablet round	Warner/Chilcott		1889**
29.	Amitriptyline Hydrochloride	Elavil	beige round tablet (50 mg)	Merck Sharp & Dohme	21*	419* 426*
	Amitriptyline Hydrochloride	Endep	orange round tablet (50 mg)	Roche	30*	435*
	Amitriptyline Hydrochloride	Amitril	blue/purple round tablet	Warner/Chilcott		1889**
36.	Hydrochlorothiazide	HydroDiuril	peach round tablet (25mg)	Merck Sharp & Dohme	22*	419*
	Hydrochlorothiazide	Oretic	white round tablet (25mg)	Abbott Laboratories	7*	404*
37.	Hydrochlorothiazide	HydroDiuril	peach round tablet (50mg)	Merck Sharp & Dohme	22*	419*
	Hydrochlorothiazide	Oretic	white round tablet (50mg)	Abbott Laboratories	7*	404*
40.	Isosorbide Dinitrate	Isordil	light pink round, scored tablet (oral 5mg)	Ives Laboratories	15*	412*
	Isosorbide Dinitrate	Sorbitrate	light green oval tablet (oral 5 mg)	Stuart Pharmaceuticals	38*	435*

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
41. Isosorbide Dinitrate	Isordil	light pink round tablet (5mg sublingual)	Ives Laboratories	15*	41**
Isosorbide Dinitrate	Isotrate	green round tablet (5mg sublingual)	W.E. Hauck, Inc.	Exhibit B-Q1	
42. Isosorbide Dinitrate	Isordil	white round scored tablet (10mg oral)	Ives Laboratories, Inc.	15*	41**
Isosorbide Dinitrate	Sorbitrate	yellow oval tablet (10 mg oral)	Stuart Pharmaceuticals	3[illegible]*	435*
Isosorbide Dinitrate	Isotrate	orange oblong tablet (10 mg oral)	W.E. Hauck, Inc.	Exhibit B-P1 annexed	-
43. Isosorbide Dinitrate	Isordil Tembids	light blue/white capsule (40 mg)	Ives Laboratories	15*	412*
Isosorbide Dinitrate	Isotrate Timecelle	orange/clear capsule (40 mg)	W.E. Hauck, Inc.	Exhibit B-P1 annexed	-
45. Amoxicillin	Larotid	brown/beige capsule (250 mg)	Roche Laboratories	30*	428*
Amoxicillin	Amoxil	blue/pink capsule (250 mg)	Beecham Laboratories	9*	405*
Amoxicillin	Polymox	pink/reddish brown capsule (250 mg)	Bristol Laboratories	10*	408*

Plaintiff's Exhibit 130A

Generic Name	Brand Name	Cplor	Distributor	1977 PDR Page No. or other source	1979 PDR
52. Nitroglycerin	Nitro Bid	purple/white capsule (2.5 mg)	Marion Laboratories	28*	41.*
Nitroglycerin	Nitrospan	green/white capsule (2.5 mg)	USV Pharmaceuticals	18*	: .*
53. Nitroglycerin	Nitro Bid	blue/yellow capsule (6.5 mg)	Marion Laboratories	28*	11.*
Nitroglycerin	Nitroglyn	pink/white speckled tablet (6.5mg)	Key Pharmaceuticals	16*	41**
57. Papaverine Hydrochloride	Pavabid	brown/white capsule (150 mg)	Marion Laboratories	20*	117*
Papaverine Hydrochloride	Cerespan	red/pink capsule (150mg)	USV Pharmaceutical	39*	426*
Papaverine Hydrochloride	Cerebid	red/clear capsule (150mg)	Saron Pharmaceutical Corp.	1381**	1512**
Papaverine Hydrochloride	Vasal	lavender/blue/white capsule (150 mg)	Tutag Pharmaceutical	39*	436*
Papaverine Hydrochloride	Pavacap	blue/white-blue capsule (150 mg)	Reid-Provident Labs., Inc.	28*	
Papaverine Hydrochloride	Pavacot	pink/brown capsule (150 mg)	C.O. Truxton, Inc.		1723**
Papaverine Hydrochloride	Pavakey	caramel/clear capsule (150 mg)	Key Pharmaceuticals, Inc.	869**	931**
Papaverine Hydrochloride	Pavacon Cenules	brown/clear capsule (150 mg)	Central Pharmacal Co.	704**	761**

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
57. (contd.) Papaverine Hydrochloride	Myobid	red/clear capsule (150 mg)	Laser, Inc.	877**	[illegible] **
Papaverine Hydrochloride	Therapav Capsules	aqua gelatin tablet (150 mg)	Cooper Labs., Inc.	-	[illegible] *
Papaverine Hydrochloride	Vasospan	red/clear capsule (150 mg)	Ulmer Pharmacal Co.	1611**	1740**
Papaverine Hydrochloride	Pavatran	orange/clear capsule (150 mg)	Mayrand, Inc.	1022**	1050**
58. 100mg Dioctyl Sodium Sulfosuccinate 30 mg Casanthranol	Peri-Colace	purple capsule	Mead Johnson	21*	418*
100mg Dioctyl Sodium Sulfosuccinate 30mg Casanthranol	Comfolax-plus	two tone green capsule	Searle Laboratories	34*	432*
59. Pentaerythritol Tetranitrate	Peritrate	light green round tablet (20 mg)	Warner/Chilcott	42*	438*
Pentaerythritol Tetranitrate	SK-Petn	white round tablet (20mg)	Smith Kline & French	36*	-
60. Pentaerythritol Tetranitrate	Peritrate	light green round tablet (10 mg)	Warner/Chilcott	1680**	1819**
Pentaerythritol Tetranitrate	SK-Petn	white round tablet (10 mg)	Smith Kline & French	36*	-

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
81. Ampicillin	Polycillin	gray/red capsule (250 mg)	Bristol Laboratories	10*	406*
Ampicillin	Penbritin	black/red capsule (250 mg)	Ayerst Laboratories	9*	403*
Ampicillin	Amcill	blue/gray capsule (250 mg)	Parke-Davis	23*	421*
Ampicillin	Pen-A	blue/yellow (250 mg)	Pfi Pharmacy	25*	424*
Ampicillin	SK-Ampicillin	yellow/white capsule (250 mg)	Smith Kline & French	36*	1625**
Ampicillin	Pensyn	dark green capsule (250 mg)	Upjohn	40*	437*
82. Conjugated Estrogens	Premarin	brown oval tablet (0.625 mg)	Ayerst Laboratories	9*	405*
Conjugated Estrogens	Genisis	white triangular tablet (0.625 mg)	Organon	23*	-
83. Conjugated Estrogens	Premarin	yellow oval tablet (1.25 mg)	Ayerst Laboratories	9*	405
Conjugated Estrogens	Genisis	white oval tablet (1.25 mg)	Organon	23*	-
85. Imipramine Hydrochloride	Tofranil	coral triangular tablet (10 mg)	Geigy	15*	411*
Imipramine Hydrochloride	Janimine	orange round tablet (10 mg)	Abbott	7*	403*

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
85. (contd.) Imipramine Hydrochloride	Presamine	light blue round tablet (10 mg)	USV Laboratories	40*	[illegible]*
Imipramine Hydrochloride	SK-Pramine	blue round tablet (10 mg)	Smith Kline & French	38*	[illegible]**
90. Amoxicillin	Larotid	beige capsule (500 mg)	Roche Laboratories	38*	426*
Amoxicillin	Amoxil	blue/pink (500 mg)	Beecham Laboratories	9*	405*
Amoxicillin	Polymox	pink/reddish brown (500 mg)	Bristol Laboratories	10*	405*
7. 20.0mg phenobarbital 0.3mg ergotamine tartrate 0.1mg belladonna alkaloids	Bellergal	pink sugar-coated	Dorsey Labs	13*	418*
20.0mg phenobarbital 0.3mg ergotamine tartrate 0.1mg belladonna alkaloids	Dolatrin	blue sugar-coated	Century Labs	704**	-
8. Diphenhydramine Hydrochloride	Benedryl	white/pink capsules (25 mg)	Parke-Davis	23*	421*
Diphenhydramine Hydrochloride	SK-Diphenhydramine	green capsule (25 mg)	Smith Kline & French	30*	1626**
46. Nitrofurantoin	Macrodantin	opaque yellow/white capsules (50 mg)	Eaton Laboratories, Inc.	808**	418*
Nitrofurantoin	——	yellow tablets (50 mg)	Zenith Laboratories, Inc.	1757**	-

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. or other source	1979 PDR
47. Nitrofurantoin	Macrodantin	opaque yellow capsules (100 mg)	Eaton Laboratories, Inc.	808**	498*
Nitrofurantoin	——	yellow tablets (100 mg)	Zenith Laboratories, Inc.	1757**	
69. 150mg theophylline 90mg glyceryll guaiacolate (guaifenesin)	Quibron	yellow capsules	Mead Johnson Co.	21*	415*
150mg theophylline 90mg guaifenesin	S10-Phyllin GG	white capsule	Dooner Laboratories, Inc.	13*	400*
74. Reserpine	Serpasil	white scored tablet (0.25 mg) (0.1 mg)	Ciba Pharmaceutical Co.	12*	408*
Reserpine	Sandril	orange tablet (0.1 mg) green tablet (0.25 mg)	Eli Lilly	992**	1055**
78. Chlorpheniramine Maleate	Teldrin	green/clear capsules (12 mg)	Smith Kline & French	37*	433*
Chlorpheniramine Maleate	Chlor-Trimeton Repetabs	light orange sugar-coated tablets (12 mg)	Schering Corp.	32*	429*
79. Chlorpheniramine Maleate	Teldrin	green/clear capsules (8 mg)	Smith Kinke & French	37*	433*
Chlorpheniramine Maleate	Chlor-Trimeton Repetabs	yellow sugar-coated tablets (8 mg)	Schering Corp.	32*	429*

Generic Name	Brand Name	Color	Distributor	1977 PDR Page No. of other source	1979 PDR
Chlordiazepoxide Hcl 10mg	A-Poxide	green/evergreen capsule	Abbott Laboratories		4[illegible]
Chlordiazepoxide Hcl 10mg	SK-Lygen	pink/orange capsule	Smith Kline & French	1488[illegible]	[illegible]
Chlordiazepoxide Hcl 10mg	None	black/tan capsule	E. R. Squibb & Sons		1638[illegible]
Chlordiazepoxide Hcl 10mg	None	black/blue capsule	Lederle Laboratories		414[illegible]
Chlordiazepoxide Hcl 10mg	Librium	black/green capsule	Hoffman La Roche	30[illegible]	426[illegible]
Chlordiazepoxide	None	light green/dark green capsules	Parke Davis		1288**

794a

Plaintiff's Exhibit 130A

DEFENDANT'S EXHIBIT 6 (INWOOD)

ARE GENERICS SAFE?

DEFENDANT'S EXHIBIT
6
INWOOD

Prepared by the New York State Assembly's Office of Legislative Oversight and Analysis for the First National Conference on Generic Drugs, Mayflower Hotel, June 23-24, 1978

Stanley Steingut
Speaker of the
Assembly

Defendant's Exhibit 6 (Inwood)

INTRODUCTION

The issues raised by this Conference are not new or unique. They have been investigated and debated for two decades. Beginning with the efforts of the late Senator Estes Kefauver, the ethical drug industry has been subjected to intense scrutiny. Senators Long, Nelson and Kennedy replowed the Kefauver ground and explored new aspects of the industry's grip over the prescribing habits of the nation's 256,000 physicians. Why, they all asked, if drugs prescribed under their generic name are identical with drugs prescribed under their trade names, do the nation's doctors, who learn to prescribe generically in college, continue to prescribe the high priced product? The issue became even more complex when doctors who used generic products in their hospital practice (where generic formularies were established to reduce costs) refused to do so in their private practice?

Some of the answers were obvious. After the second year in medical school, the physician receives most of his drug information from salesmen. The medical journals he reads are often the handmaidens of the drug industry, dependent on their advertising to survive. Even the Journal of the American Medical Association sold out to the advertisers when the public relations firm it hired told them to terminate their prestigious Council on Drugs and to change their outspoken support of generic prescribings if they wanted to increase their advertising revenues. As late as last month the AMA Journal, bulging with drug company ads, admonished physicians---in both a misleading article and an editorial,---not to trust generic prescribing.

That misleading article, we are sorry to note, made the national news wires (without dissenting comment), was quickly translated into local stories by AMA doctors and now appears as a standard "letters to the editor" item in small town newspapers. The federal government is still slowly grinding out a response which, when it appears, will do little to rectify the damage. The "big lie", heavily promoted, has been the technique of this industry. Their multi-billion dolcar advertising budget, and all that implies, hangs as a heavy hammer over the heads of anyone challenging the industry. In past years, that budget drifted into politics and wiped out the PMA's political opponents. Those days are <u>almost</u> over.

The generic battle had its origins with the military in the fifties. A tough old admiral, angered at the high price of prescription medicine, and the refusal of American companies to sell him equivalent products at lower prices, went overseas for bids and, in so doing, set in motion a process, generic prescribing, which has now spread to all military and government purchases (with the President's Office of Management and Budget assigning the quality assurance guarantees to the FDA),

Defendant's Exhibit 6 (Inwood)

to most public and private hospitals, and to some public spending and third party payment plans. Left out in the cold were the families who earned over $5,000 a year, the large American middle class.

To block the spread of the concept to consumers, the PMA, using a political arm, raised the scare flag of "counterfeit drugs", assembled a multi-million dollar warchest, and, within a few years, every state in the Union had passed both anti-substitution and anti-advertising laws. A pharmacist, no matter his training, or a consumer, no matter his desire, could not get a generic drug substituted for the higher priced trade name product (although, in some states, it was permissible to substitute the trade name product for the generic).

With that victory in hand, the industry focused its multi-billion dollar campaign on the physician. Ironically, physicians learn to prescribe generically in medical school and most medical schools follow the example of Dr. Robert H. Ebert, Dean of Harvard Medical College who recently sent a memo to the Faculty of Medicine stating:

> "Almost all studies show that generic drugs and name-brand drugs are indistinguishable in therapeutic effectiveness, purity or accuracy of labeling.
>
> "The exaggerated and probably false distinction between brand-name and generic drugs claimed in advertising by drug firms is regrettable.
>
> "The Faculty of Medicine should maintain its awareness of such questionable practices in the marketing of drugs and counteract this practice through their own habits of prescription writing and those they teach to their students."

But twenty years of brainwashing is difficult to unwind. When the nation was unaware of its practices, the detailmen of the industry (operating under a budget which ranges between $3,000 and $5,000 for every physician in the country) bought their way into the doctor's office with a list of replenishable free samples, presents and cash and dispensed not only incomplet and overstated claims about his products, but told and retold scare stories about generic failures, most of them distorted, taken out of context, or told without reference to the misconduct of the major companies (so clearly outlined in Senator Nelson's statement in this booklet). In New York one major firm's ampicillan plant was closed down for contamination. Another was repeatedly cited for violations and did little to correct the problems.

Against the FDA's scientific and systematic review of drug products (the most thorough testing available in the world today) single episodes of doctors were told, stories which were

not subject to independent scientific evaluation (an example of this technique can be found in the Private Practice article used in this booklet).

Dr. Donald Kennedy, FDA's new and aggressive Commissioner, has repeatedly said that their review shows no substantial difference between the recals of trade and generic houses when they come within the scope of either ANDA's and NDA's, except, in terms of volume, the major companies' recalls are astronomical when compared to their smaller generic counterpart companies.

The story became even more absurd when the New York State Assembly, in its inquiry into "branded generics" learned, under oath, that the majors frequently use the smaller generic companies to make their products---at price differentials of 400 percent (see the articles in this booklet on branded generics). Some companies, embarrassed by the conflict with their physician's campaign, hide the fact that the smaller companies produce their trade name products. To get around new state laws requiring manufacturers disclosure, they place "a man in the plant" who stands around when the generic company runs their product down the assembly line. The generic houses are sometimes co-opted in their criticism of their large benefactors because of this process. One generic manufacturer, who is attending this Conference, summed it up neatly when asked to appear, under subpoena, before the New York Assembly: "What do you want me to do, cut off the arm that feeds me?"

The one-to-one lobbying of detailmen, and the "paid cooperation" of some medical journals, is enough to stop a new state law in its tracks. In New York, where substitution of a lower priced generic is mandated if the physician signs on a line on the right hand side of the prescription (his normal procedure, we were told), the physicians are blocking effective implementation of the law, by the simple process of signing on a line to the left which was designed for singular situations in which a physician believes his patient, for unique reasons, needs a particular product, even though it is medically interchangeable with a lower priced counterpart drug. During the first two months of the New York law, three out of four physicians are signing to the left. They are the targets of a temporarily successful campaign of the detailmen and the pharmacists, who had bitterly opposed the new law. In Michigan and Wisconsin, as you will learn from Dr. Goldberg during the Conference, over 95 percent of the physicians permit substitution and do not exercise their option to write across their prescription "dispense as written". On the surface, it looks as if the doctors are lazy; require them to write it out and they will comply. The legislative answer, it seems, is not that simple. In Wisconsin and Michigan the option to substitute rests with the pharmacist who, the study indicates, is not substituting to the extent intended by the state legislation. There the pharmacist is the target of the drug companies.

The lesson is clear: the ability of the drug companies to block implementation of state laws is not to be underestimated. A law on paper means little if the consumer doesn't share the benefits of substitution. The political victory is not won when the Governor signs the law.

The industry is also effectively using the "quiet clause" technique of undercutting state laws. As you will learn from reading the Wall Street summary of the impact of state laws, industry slips little clauses into state legislation which have the effect of preventing widespread substitution. It now appears that the Federal Trade Commission, and HEW are moving into this void with model laws. We might even get a little healthy competition between the two segments of government rushing in to help the consumer. In the past, neither agency has been of much use to the consumer on this issue. New leadership, and the initiative of the Carter administration on cost containment, promises a new day. The drug industry lobbyist-lawyers, who have had free access to the back door of the White House since the days of Dwight Eisenhower are finding deaf ears at the White House these days, due in part, we believe, to Carter's populist instincts, which, in this case, parallel those of Louisiana's Senator Long, a man who is not exactly the hero of consumers on tax or oil issues.

Industry has some new tactics up its sleeve. They want major changes in the authority of FDA to regulate their practices in breakthrough drugs and overseas sales (which account for 40 percent of their market) and to keep their executives out of jail if they engage in corrupt practices. These items, and the otherwise worthwhile aspects of the Drug Reform Act of 1978, will be reviewed at the Conference. This booklet contains a review of the law and an "in-house" consumer analysis of its provisions.

The industry is moving towards the concept of higher priced branded generics to slip under the substitution legislation under the theory that if you can't beat them, join 'em. They are now charging higher prices for single source products. They are about to surreptitiously push for "consumer legislation" which will allow Joe Citizen to come into a pharmacy and say "Don't give me any of those inferior generics, give me (trade name) tetracycline!" That this is a 180 degree turnabout of their current tactics doesn't even phase the industry. Documents which have been reviewed by the New York State Assembly reveal that some of the budget now allocated to the medical press, will be shifted into public media, as per aspirin, so consumers will become addicted to the concept that generics are unsafe and the only assurance is in trade name products. If you watch carefully, you can see the beginnings of this campaign on both national television and in local advertisements. New York State has officially complained to FDA and FTC on specific advertisements, but

it is much like plugging up a hole in the Dutch dam with your thumb.

The best of all possible worlds would be the course advocated by Senators Long and Nelson, the establishment of a "Formulary of the United States" which would make value judgments on the effectiveness and need of drug products and peg federal reimbursements to those scientific decisions. That approach would not only attack the issue of over-pricing, but the more important issue of over-prescribing.

State Formularies are not filling that gap. The New York State Formulary of medically interchangeable drugs won the approval of the FDA because of courageous men like Dr. Marvin Seife and his colleagues within the FDA, the quiet intervention of Senators Kennedy and Nelson, and the action of the new Commissioner, Don Kennedy. But ours was the most conservative of lists. Massachusetts and Vermont have more complete forumlaries. Our strategy then, as now, was to start the process, get other states to stand on the little piece of ground we had cleared, and, eventually, have the federal government do what it should have done years ago, put out a list of interchangeable drugs with prices alongside the drugs and promulgate this material to the physicians of this country in one last effort to appeal to their intellect before moving towards restrictive regulation which both physicians and legislators dislike. In New York, the physicians have already been warned by the Speaker of the Assembly, Stanley Steingut, that unless they shape up and follow the intent of our law, they are in for stricter regulation.

The states are in no position to fight the drug companies one-by-one. We need an aggressive HEW, FDA and FTC to stand alongside a Congress which has found its courage, and a Justice Department which for the first time in two decades is moving in on the drug companies. With their help, and our state laws, prices can tumble dramatically and end, once and for all, the generic deception which has not only hurt consumers, but prevented the American drug industry from engaging in more meaningful research.

As for this booklet, it comes from my files, notes and all. These were the articles and leads which helped us keep track of the industry. It was through these articles that we found our friends and learned about our enemies (Wall Street, believe it or not, is the most honest commentator around).

If you need help in the months ahead, or can't read an article enclosed, let us know.

New York will publish a drug newsletter which, if you like, can be sent to you on a regular basis.

The contact point is: Office of Legislative Oversight and Analysis, Room 5026, Two World Trade Center, New York, New York 10047.

Excuse the informality of this introduction and the booklet, but it's our style.

William F. Haddad

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P r e s e n t:

WILLIAM HADDAD

* * *

THE CHAIRMAN: Good morning ladies and gentlemen.

My name is Harvey Strelzin and I am chairman of Consumer Affairs and Protection.

For 20 years the major drug manufacturers have successfully maintained that drugs prescribed under their generic names are ineffective and unsafe.

In that time they have spent billions of dollars to promulgate that untruth. They have co-opted and corrupted large segments of the medical profession and the medical media with these arguments.

Theirs was not a scientific concern. Theirs was a search and a reach for unwarranted profit based on the promulgation of these falsehoods.

What they have done, we are about to undo. It will not be an easy unwinding. It will take time and effort, and it will take the full cooperation of the public media.

What we must unwind is no less than a 20-year brainwashing of the medical profession.

Doctors who first learn of drugs by their generic names are slowly seduced by the drug industry's detail men -- the main channel for the flow of medical information -- and the drug industry's promotion campaign into believing that prescribing generically is unwise, unsafe, ineffective and

dangerous.

The busy doctor -- who cannot be completely obsolved of his role in this sordid matter -- has allowed himself to be seduced into writing prescriptions which cost their patients three to seven times as much for a drug as need be paid.

There were times when these differences ran as high as 400 percent. And there were times that vital medicines could not be used by the poor and the elderly because they could not afford them.

Today we will introduce into evidence a list of safe, effective and interchangeable drugs which should become the bible of all state agencies, all doctors and all pharmacists. Each manufacturer on that list has been approved by the Food and Drug Administration to produce, under inspection, a drug which is completely and safely interchangeable with the reference drug in its category.

This is the list the drug industry said did not exist. This is the list that the drug industry said could not be produced. This is the list which we have cold from the Food and Drug Administration and it has been certified by Dr. Donald Kennedy, the Commissioner of the Food and Drug Administration, as the certified list of safe, effective and interchangeable drugs.

We have our first witness today, Dr. Seife, who will testify to some of the monumental questions which will be posed to him and which will indicate for the first time that these drugs are safe, effective, interchangeable and they are generic

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and may be used in the place of brand-name drugs.

To that end, we have through our director here, Bill Haddad, we were able to cull this list which has now been made available to the people of the State of New York, to the consumer and in accordance with the bill that was passed in the Assembly, which we hope will be passed in the New York State Senate, we will have a list -- a formulary -- set up by the Commissioner of Health of the State of New York which will be a compilation of these generic drugs which has been taken from the Food and Drug Administration and certified as safe and interchangeable.

Dr. Seife, will you please take the witness stand.

M A R V I N S E I F E, having been duly sworn by the Chairman, testified as follows:

EXAMINATION BY MR. HADDAD:

Q. Would you state your full name and your affiliation.

A. My name is Marvin Seife. I am a physician with the Food and Drug Administration in the capacity of Director of Generic Drug Monographs, Bureau of Drugs.

Q. Dr. Seife, have you reviewed this list of compilation?

A. Yes, very actively so.

Q. As you know, we plan to submit this to the industry and to all the companies mentioned and then back to the FDA for final purification to take out any typographical errors.

Within that context would it be fair to say that this list represents, in the first instance, two categories of prescription drugs, those which can be purchased from only one source and those which can be purchased from more than one source?

A. Yes.

Q. Let us focus for a moment on the multi-source drugs.

Is it true that each of these drugs is matched against a reference drug?

A. Yes.

Q. Is it true that each of the drugs listed is interchangeable with a reference drug?

A. Yes.

Q. Is it true that each of these drugs is safe?

A. Yes.

Q. Is it true that each of these drugs is effective?

A. Yes.

Q. Although we both recognize that the bioequivalent and bioavailability arguments have been misused by the drug industry to postpone the use of generics, is it not true that all of the drugs listed in group one on this list -- what the FDA calls the vast majority of the drugs -- are both bioequivalent and bioavailable, or in short, completely therapeutically identical?

A. Yes.

Q. Can a doctor be assured when he prescribes a certain drug and it is here, that it is interchangeable with its reference drug?

A. Yes.

Q. Can a pharmacist, if he were allowed to by law, safely substitute a generic product from this list for a trade name prescri by the doctor?

A. Yes.

Q. This list includes both drugs and manufacturers.

Can you tell us if there is any difference in the way

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THE ASSEMBLY
STATE OF NEW YORK
ALBANY

WILLIAM F. HADDAD,
Director

DAVID E. LANGDON,
Assistant Director

Office of Legislative Oversight
and Analysis
Room 942
State Capitol
Albany, New York 12224

This memo was prepared for legislators to use in conducting a survey within their own districts. Many did so and received widespread local media coverage because of the wide differentials in the price of generic and trade name products. Since the survey, there is more competition in the anti-biotic area, but you will still discover price differences of over 100 percent. The differences for chlordiazepoxide (Librium) are astronomical. While over-all averages are important, you can make the most impact when you cite prices on drugs in common use.

February 23, 1978

TO: Legislators

FROM: William F. Haddad
Office of Legislative Oversight and Analysis

RE: How to Conduct a Local Prescription Drug Survey

The New York State generic substitution law becomes effective April 1, 1978. (Chapter 776, Laws of 1977). Under the new Law, the pharmacist is required to substitute an equivalent, less expensive generic drug every time a high priced trade name drug is prescribed. The only exception occurs when the physician exercises his right to sign to the left of the prescription pad, over the printed statement, "Dispense as Written".

The price difference between the brand name and generic at the wholesale level is fantastic. Nothing in the law says the pharmacists has to pass on those wholesale price differentials to the consumer. For this law to provide big savings to the consumer, it will mean discriminating consumer shopping and effective monitoring. Local Prescription Drug Surveys are the start.

Now might be an ideal time to survey pharmacies in your area for drug price comparisons. A well conducted and well publicized survey will accomplish two objectives:

(1) it will alert consumers to the potential savings under the new law, and

(2) it will alert all of us to the problems which may undermine the intent of the law, and prevent consumers from fully benefiting from the potential savings.

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The lead on a press release announcing the survey results may read: "A prescription for Achromycin V filled on the last day of March will cost you $12.04. The same prescription filled the very next day, April 1, 1978, will cost you only $3.89".

The Issues

In conducting the survey, you and your staff should be alert to the following issues.

1) Branded Generics. In an attempt to subvert the intent of the New York State Law, the major brand name companies have introduced their own lines of generic drugs, the so-called "branded generics". Branded generics are not true generi s. Survey after survey has shown that they do not and will not provide the extensive savings called for by the Law and available from true generic drugs.

Ask the pharmacist the name of the manufacturer of the generic drug he is dispensing. The pharmacist may not realize that, in dispensing a branded generic, he is transgressing the intent of the New York State Law.

Note: You may decide to expand your survey to include the prices of the branded generics, as well as the prices of generic and brand name products.

2) Price Posting. Under the Education Law, the pharmacist is required to post the prices he charges for each of the 150 most frequently purchased drugs. Spot checks have shown that many pharmacists are not displaying the price chart. If the chart is not "conspicuously posted" find out why.

Even where posted, the chart will not provide all of the information necessary for the conduct of the survey. Some price quotes will have to be obtained directly from the pharmacist. The pharmacist is not required to quote prices over the phone, though many will; the pharmacist is required to answer all in-store questions regarding the prices of his drugs.

This section of the Education Law is presently being reviewed for amendment. It has been proposed that a comparative method of price listing would be more useful in light of the new Law.

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3) Liability. Pharmacists have been expressing concern over the liability of the pharmacist under the new law. Their fears are the result, at least partly, of scare campaigns initiated by some of the major drug companies. The fact is that, though generic substitution laws have been in place for five years, not a single case has ever been brought to court. Brand name manufacturers promise pharmacists "product liability protection", and say so prominently in literature and advertisements, but representatives from three major firms, when questioned at the recent Assembly hearings, could not think of a single instance in which a claim had been made on the policy.

The Committee on Consumer Affairs and Protection expects to hold hearings on the issue of pharmacists' liability later during this session.

Conduct of the Survey

Attached is a list of 15 drugs for comparison in a price survey. The drugs were selected on the basis of (a) availability from more than one source (i.e., no longer covered by patent) and, (b) frequency of use.

Select the drugs to be compared. Print them on the survey form (sample survey form attached).

Select 8 - 12 pharmacies in your area. Using the form, record the prices charged for each drug by each pharmacist. Be specific about dosage form and quantity.

When all prices are recorded, transcribe the results to a master sheet. You will be tracking two statistics for each drug: (1) the average price of the generic product compared to the average price of the brand name product, and, (2) the lowest priced generic found anywhere, compared to the highest priced brand name found anywhere.

The first statistic, the difference between the averages, indicates the savings that the average shopper can expect under the new law. The second statistic, the difference between the extremes, indicates the savings a particularly avid shopper will find.

When all statistics are assembled, the difference in price between the generic and the brand name products may be shown either as a dollar "Savings" figure, or as a percentage "% Difference" figure.

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Caution

1) Our past surveys have documented that many pharmacists do not carry generic equivalents. Beginning April 1st, they will have to. If you do a survey before April 1st, make sure to note those instances when generics are not available.

2) Always make sure to record the manufacturer's name of the generic drug when getting a price quote. Knowing the manufacturer's name is as important as knowing the price.

Notes

1) Antibiotics (the penicillins, tetracyclines, etc.) are particularly dramatic subjects for price comparisons because all antibiotics, generic and trade products alike, are batch-tested by the FDA before they may be released to the public. Only one other drug, Insulin, is similarly batch-tested.

2) If you want to particularly dramatize the issue for television, have a friendly doctor write out several prescriptions in both the trade and generic names, then purchase the drugs in the same pharmacy.

If you have any questions please call: David Langdon, (518) 472-3473 or Jean Callahan (212) 488-3728.

SAMPLE SURVEY FORM

Pharmacy _____

Address _____
Telephone No. _____
Date _____

GENERIC DRUGS		MANUFACTURER	PRICE	TRADE NAME DRUGS	MANUFACTURER	PRICE
Amitriptyline	25mg tabs/100			Elavil	MSD	
Ampicillin	250mg caps/20			Polycillin	Bristol	
Chlordiazepoxide	25mg caps/100			Librium	Roche	
Chlorothiazide	500mg tabs/100			Diuril	MSD	
Conjugated Estrogens	1.25mg caps/100			Premarin	Ayerst	
Erythromycin	250mg caps/100			E-Mycin	Upjohn	
Meprobamate	400mg tabs/100			Equanil	Wyeth	
Oxytetracycline	250mg caps/100			Terramycin	Pfizer	
Papaverine	150mg caps/100			Pavabid	Marion	
Penicillin VK	250mg tabs			V-Cillin K	Lilly	
Prednisone	5mg tabs/1000			Paracort	Parke Davis	
Propoxyphene	65mg caps/100			Darvon	Lilly	
Reserpine	.25mg tabs/100			Serpasil	Ciba/Geigy	
Sulfisoxazole	500mg tabs/100			Gantrisin	Roche	
Tetracycline	250mg caps/100			Achromycin	Lederle	

Compiled by _____

DRUGS FOR COMPARATIVE PRICE SURVEY

GENERIC NAME	BRAND NAME & MANUFACTURER		DOSAGE	QUANTITY
1. Amitriptyline HCL (an anti-depressant)	Elavil	MSD	25 mg tabs	bottles of 100
2. Ampicillin (antibiotic)	Polycillin	Bristol	250 mg caps	bottles of 20
3. Chlordiazepoxide HCL (sedative)	Librium	Roche	25 mg caps	bottles of 100
4. Chlorothiazide (diuretic)	Diuril	MSD	500 mg tabs	bottles of 100
5. Conjugated Estrogens (hormone)	Premarin	Ayerst	1.25 mg caps	bottles of 100
6. Erythromycin (antibiotic)	E-Mycin	Upjohn	250 mg caps	bottles of 100
7. Meprobamate (tranquilizer)	Equanil	Wyeth	400 mg tabs	bottles of 100
8. Oxytetracycline HCL (antibiotic)	Terramycin	Pfizer	250 mg caps	bottles of 100
9. Papaverine (anti-senility)	Pavabid	Marion	150 mg caps	bottles of 100
10. Penicillin VK (antibiotic)	V-Cillin K	Lilly	250 mg tabs	bottles of 100
11. Prednisone (anti-inflammatory)	Paracort	Parke Davis	5 mg tabs	bottles of 1000
12. Proposyphene (analgesic)	Darvon	Lilly	65 mg caps	bottles of 100
13. Reserpine (antihypertensive)	Serpasil	Ciba/Geigy	.25 mg tabs	bottles of 100
14. Sulfisoxazole (anti-infective)	Gantrisin	Roche	500 mg tabs	bottles of 100
15. Tetracycline HCL (antibiotic)	Achromycin	Lederle	250 mg caps	bottles of 100

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NEW YORK STATE DRUG PRICE SURVEY
Trade Name Drug Prices vs. Generic Drug Prices
JUNE, 1977

In the second week of June, 1977, the NYS Assembly Office of Legislative Oversight and the New York Public Interest Research Group surveyed the prices paid for nine frequently prescribed drugs in six New York State communities. Eight pharmacies were polled in each of the six communities.

The six communities were:

Albany
Binghamton
Buffalo
New York City
Rochester
Syracuse

The prescription drugs were:

price/100		('76 rank)	GENERIC EQUIVALENT
Equanil	Wyeth	90	Meprobamate
Hydropres-50	MSD	72	Hydro & Reserpine
Librium	Roche	8	Chlordiazepoxide
Lomotil	GS Searle	31	Diphen & Atropine Sulfate
Pavabid	Marion	58	Papaverine
Ser-ap-es	CIBA	40	Hydralazine HCl & others
Darvon Comp-65	Lilly	15	Propoxyphene Compound
Hydrodiuril	MSD	6	Hydrochlorothiazide
price/20			
Polycillin	Bristol	121	Ampicillin

Survey results were analysed community by community; community figures were compiled to obtain a statewide profile of drug purchase prices.

The purpose of the survey was to obtain current information regarding the price differences between generic drugs and their brand name counterparts, on a community by community basis.

NEW YORK STATE SURVEY: PRICES PAID FOR NINE FREQUENTLY PRESCRIBED DRUGS

TRADE NAME	GENERIC NAME	average highest price for trade, all stores	average lowest price for generic, all stores	AVERAGE DIFFERENCE between gen & trade, all stores	PERCENT DIFFERENCE between gen & trade, all stores
price/100					
Equanil	Meprobamate	$11.57	$2.50	$6.06	342%
Hydropres-50	Hydro & Reserpine	14.68	4.91	6.48	232
Librium	Chlordiazepoxide	11.53	3.74	3.85	203
Lomotil	Diphen & Atropine Sulfate	16.18	8.31	6.38	177
Pavabid	Papaverine	15.23	5.23	5.90	213
Ser-ap-es	Hydralazine HCl & others	13.53	6.36	6.39	200
Darvon Comp-65	Propoxyphene Compound	11.90	3.67	3.85	205
Hydrodiuril	Hydrochlorothiazide	9.24	2.70	3.09	215
price/20					
Polycillin	Ampicillin	7.08	2.18	2.45	212

-prices current as of June, 1977
-survey conducted by:
Assembly Office of Legislative Oversight & Analysis, and the New York Public Interest Researc Group

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THE ASSEMBLY
STATE OF NEW YORK
ALBANY

WILLIAM F. HADDAD
Office of Legislative Oversight
and Analysis
World Trade Center Two
Room 5028
New York, New York 10047

REPORT ON BRANDED GENERICS

FEBRUARY 1978

Jean Callahan
Dee Fensterer
David Langdon
William Haddad

WHAT ARE BRANDED GENERICS?

A subtle and little understood development threatens to undermine the intent and effectiveness of New York State's new generic substitution law.

The development is at once simple and ingenious.

While ferociously resisting for the last ten years the trend towards generic substitution, the major brand name firms at the same time anticipated the inevitable. While the left hand maligned generic manufacturers, the right hand began to provide for the production of the major firms' own generic products.

One or two companies made the first strategic decision; other companies followed. By now, in 1978, a growing segment of the prescription drug market is made up of generic drugs sold by brand name firms, that is, branded generics.

WHY BRANDED GENERICS?

Having prepared for the inevitable, trade name companies are in an ideal position to promote and benefit from their branded generic lines. At least five states (New York among them) now require generic substitution. Another 28 states permit generic substitution. The remaining states have tried, or are now trying, to pass similar legislation. Generic drugs have become widely identified with consumerism, and with lower cost. Chain stores are beginning to devote entire pages of news-print to informative advertising on generic drugs.

At the same time, there remains a lingering distrust of generic firms and a nearly instant identification with the major trade name companies (the result of successful

industry campaigns to discredit and mark as inferior all non-trade products.)

This is the vacuum which the manufacturers of branded generics intend to fill: on the one hand, the positive attitude towards generics; on the other hand, the uncertainty still surrounding the small generic manufacturer.

BRANDED GENERICS: AT WHAT PRICE?

Since the introduction of branded generics, the Office of Legislative Oversight has closely observed pricing trends. Surveys conducted at both the wholesale and the retail level (July 1977 and January 1978) have documented what close observation suggested: branded generics represent a small savings over brand name drugs, but do not begin to approach the savings available from the generic equivalent. We have seen the development of a three tiered pricing system, with branded generics falling between the low priced generic and the high priced brand name drug.

And what is the consumer paying for when he purchases the branded generic at a price more than 400 percent greater than the generic product? Is the price worth what a Lederle executive called the "value added" which derives from the trade name label? Is the branded generic different from, better than, the generic?

Two sets of facts should help to answer the question: what does the federal agency responsible for regulating the drug industry say? And, who actually manufactures the branded generics?

WHAT DOES THE FDA SAY?

Dr. Donald Kennedy, Commissioner of the FDA, appeared on nationwide television on January 24, 1978 to endorse the NYS interchangeable formulary and to respond to the question: Do the major brand companies exercise better quality control than the small generic companies in the manufacture of their trade name or generic drugs? Dr. Kennedy responded: "Our information does not suggest any thing of the

sort. We've maintained compliance records on all of the firms that make drugs. As far as our records are concerned, large and small firms, brand name firms and generic firms, have indistinguishable records of performance."

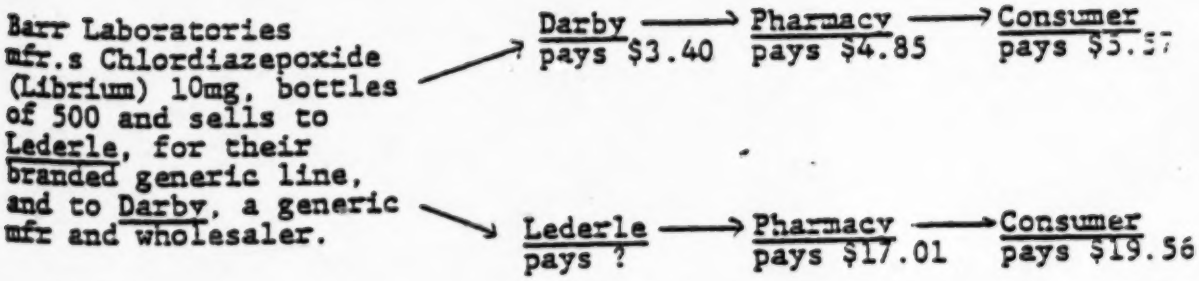
WHO MANUFACTURES THE BRANDED GENERICS?

When the trade name firms expanded into generics, they did not increase the capacity of their own facilities. They subcontracted the work out to generic firms. A series of contradictions have sprung from this first irony.

PMA companies attacking generic firms as inferior and unreliable could not let it become known that a growing number of their products were actually being manufactured by the generic houses.

Our office has documented cases in which the generic manufacturer sells his product to both a trade name house and to a wholesale distributor. Same facility, same equipment, same raw materials, same personnel, identical

specifications and procedures, but what happens to the prices paid by consumers?



In his local pharmacy the consumer will pay 2 to 3 times more for the branded generic than he will for the identically manufactured drug, sold under the generic manufacturer's own name.

Lederle Laboratories testified before the Assembly's Committee on Consumer Affairs & Protection that of 83 drugs in their "standard products" line (generics), all but possibly two are manufactured under contract by outside generic firms. Lederle is one company which prints on its labels "manufactured by_____, distributed by Lederle". Other drug companies do not disclose the actual manufacturer of the branded generics.

Major firms commonly avoid manufacturer disclosure by a legal fiction known as "man-in-the-plant". The trade name firm

leases the generic plant for the hours or day. it takes to produce its product. For the length of time the batch is run, a single employee from the contractor sets up an office in the generic plant. Man-in-the-plant arrangements have, till now, successfully eluded state statutes which require disclosure of the true manufacturer.

CONCLUSION

The issue is confusing enough that the consumer may easily obtain a branded generic, and believe himself to be achieving the full potential for savings under the new law. As our surveys have conclusively indicated, he will not be. He will at best gain a marginal savings over the old, high priced, trade name drug.

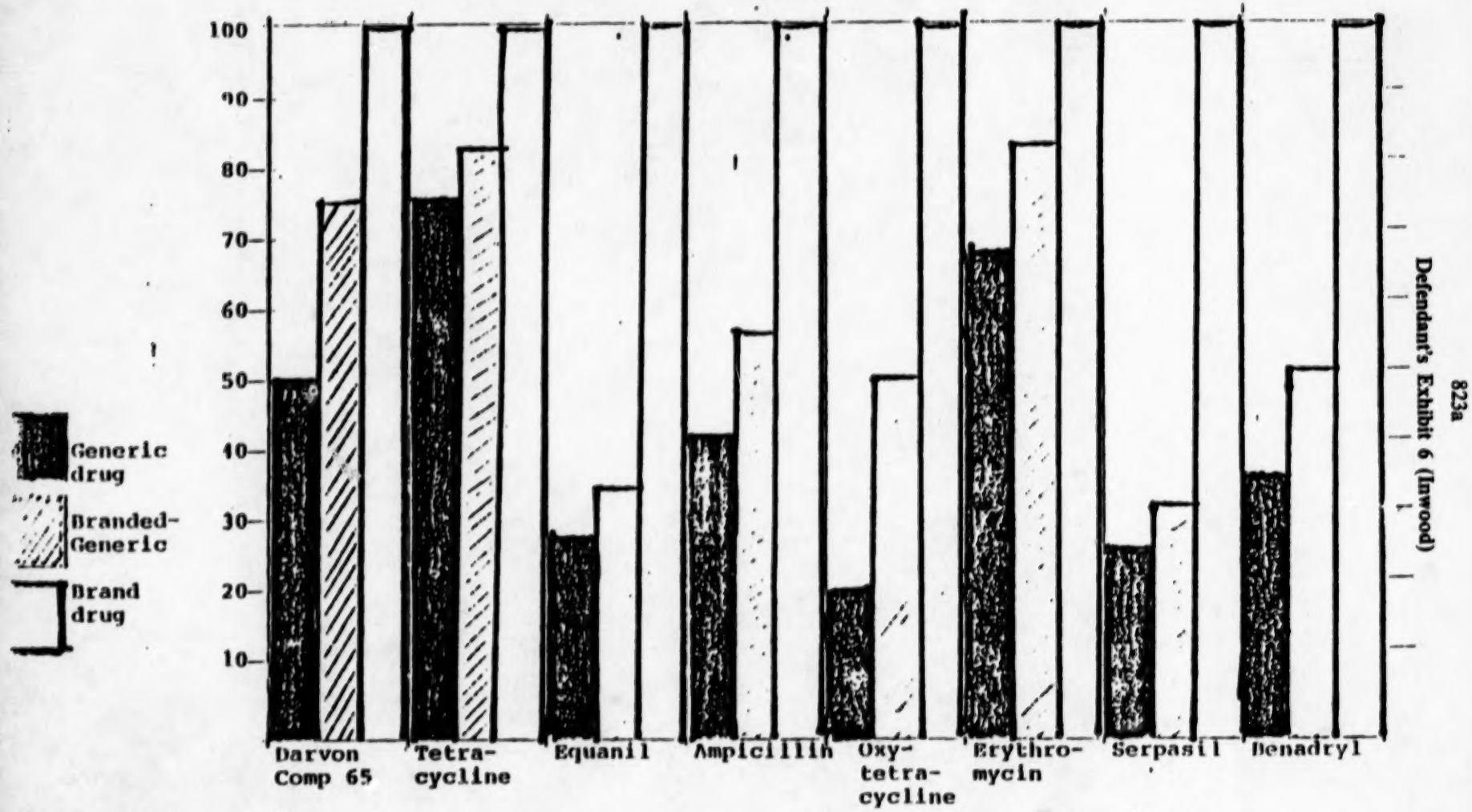
Discussions have indicated that pharmacists, too, are uncertain about the safety, effectiveness and interchangeat of generic vs. branded generics. The trade name manufacturers are responsible for this uncertainty and are employing

unethical tactics to sustain it. A recent scare film, made and distributed by Pfizer, warns the pharmacist of the extensive lawsuits he will be liable for when he substitutes generics in conformity with the new law. The film has no basis in fact. There is not one documented instance of a successful lawsuit or claim resulting from generic substitution.

To counteract this type of industry attack, the Legislature must continue its efforts through public hearings and media presentations, to insure that the State's consumers receive the benefits intended by this important Legislation.

BRANDED GENERICS

THREE DIFFERENT PRICES FOR THE SAME DRUG



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DRUG NAME	(BARR)	
Dexamethasone Tablets .75 mg/100 (cortisone-like drug for relief of tissue inflammation)	$8.00	$11.98
Chlordiazepoxide HCL Capsules 10 mg/100 (a sedative)	$2.49	$7.98
Quinidine Sulfate Tablets 200 mg/100 (cardiac depressant)	$13.99	$14.99
Sulfisoxazole Tablets 500mg/100 (Anti-infection drug)	$2.99	$4.99
Hydralazine HCL Tablets 50 mg/100 (Anti-hypertensive drug)	$2.99	$5.99
Hydrocortisone Tablets 20 mg/100 (cortisone-like drug)	$6.99	$8.99
Promethazine HCL Tablets 25 mg/100 (antihistamine)	$1.99	$3.99
Prednisone Tablets 5 mg/100 (cortisone-like drug)	$2.95 (Philips Roxane)	$2.99 (SKF)
Triamcinolene Tabs 4 mg/100 (cortisone-like drug for relief of tissue inflammation)	$5.99	$11.98
Dexamethasone Tablets .75 mg/100 (cortisone-like drug for relief of tissue inflammation)	$8.00	$14.99
Quinidine Sulfate Tablets/100 200 mg/100 (cardiac depressant)	$13.99	$19.99

Defendant's Exhibit 6 (Inwood)

LEDERLE LABORATORIES - Approved Drugs Actually Manufactured by Small Firm

Dexamethasone Tablets 0.25,0.75,1.5 mg ("Decadron" MSD)	Barr Laboratories
Prednisone Tablets 5,20 mg.	"
Sulfisoxazole Tablets 500 mg ("Gantrisin" Roche)	"
Hydrocortisone Tablets 20 mg	"
Promethazine HCL Tablets 25,50 mg ("Phenergan" Wyeth)	"
Chlordiazepoxide HCL Capsules 5,10 25 mg ("Librium" Roche)	"
Quinidine Tablets 200 mg	"
Hydralazine HCL Tablets 25 mg ("Apresoline" Ciba)	"
Probenecid Tablets 500 mg	Mylan Pharmaceuticals
Chlorothiazide Tablets 250, 500 mg ("Diuril" MSD)	"
Propantheline Bromide Tablets 15 mg ("Pro-Banthine" Searle)	"
Reserpine Tablets 0.25 mg. ("Serpasil" Ciba)	Cord Laboratories
Rauwolfia Serpentina Tablets 50, 100 mg ("Raudixin" Squibb)	"
Nitrofurantoin Tablets 50,100 mg ("Cyantin" Lederle) ("Macrodantin" Eaton)	Ketchum Laboratories
Imipramine Tablets 10,25,50 mg ("Tofranil" Geigy)	Biocraft Laboratories

Defendant's Exhibit 6 (Inwood)

Companies' Packaging of Generic Drugs Is Called a Threat to Substitution Law

By RALPH BLUMENTHAL

Major pharmaceutical companies are steadily moving into the marketing of generic drugs, igniting fears among New York State legislative and consumer representatives that the state's new cheaper-drugs law is about to be undermined and the public deprived of expected cost savings.

Industry leaders acknowledge what one called "a big push" toward generic, or nonpatent, standard formula drugs. But they deny that the growing marketing of generic drugs in trade-name packages amounts to any attempt to circumvent the law that goes into effect April 1. Rather, they maintain, the advent of such so-called "branded generics" represents the best of both worlds for the consumer —trade-name products at cheaper prices.

The conflicting positions are producing a new furor over an issue that appeared to have been settled with enactment of the generic-drug law last Aug. 11. . .

[illegible] Swartz No. 46 Ins A Drugs B3 [illegible] 2d graf, beginning: Industry leaders

At stake is a hefty share of the estimated $10 billion that Americans spend on pharmaceuticals each year,—a market in which generics now account for about $2.7 billion, up an estimated 30 percent between 1972 and 1976, according to Legislative testimony.

The law requires the 12,000 pharmacists in the state to fill prescriptions starting April 1 with cheaper counterparts of patented trade-name drugs—that is, with generics in most cases—unless the physician specifically directs otherwise. He does this by signing his name on a special part of the prescription blank.

For example, a doctor may prescribe Terramycin, a trade-name antibiotic made by Pfizer. Under the new law, unless the doctor made it clear that he specifically wanted that trade-name drug, the pharmacist is required to substitute any cheaper counterpart that is certified as equivalent by the Food and Drug Administration. That could be oxytetracycline, the generic counterpart of Terramycin.

In this case, according to data collected by the state's Office of Legislative Oversight and Analysis, the savings to the consumer would be considerable.

A bottle of 100 capsules of 250 mg. oxytetracycline was priced at $5.49. The same quantity of Pfizer's Terramycin was selling for $29.99.

But the advent of branded generics has injected a new element. Now oxytetracycline is sold packaged by Parke Davis & Company. It was selling for $14.99, the legislative office found.

Ordinarily, the study noted, the pharmacist might still select the cheapest counterpart. But since the law requires only the substitution of a cheaper equivalent—and partly because of what the study called an industry campaign of "lies" and "deception" about the safety of unbranded generics—the pharmacist could turn to the growing lines of medium-price branded generics rather than the cheaper alternative.

In recent hearings, interviews and memos, the legislative office, directed by William F. Haddad, and the chairman of the Assembly's Consumer Committee, Harvey Strelzin, Democrat of Brooklyn, have raised an alarm over what they depict as an effort to "subvert" the law with such branded generic drugs.

Assemblyman Strelzin said at a legislative hearing on Jan. 12: "Branded generics are nothing more or less than generic drugs in a trade-name bottle. In many if not most instances they are produced by a generic house for the trade-name company. The only difference is price.

"If this attempt to evade the New York State law is not met head-on, gains to the consumer forecast under our law will all but be wiped out."

What it amounts to, said Robert Egan, until recently acting commissioner of New York City's Department of Consumer Affairs, "is an attempt on the part of the major drug companies to have their cake and eat it too."

Reached in Washington, the industry's leading national representative, C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association, said in response: "There's no doubt a big push toward genericism in the drug business. But I can't see how the consumer is being disadvantaged, when he's getting a quality product with a brand name at a lower price."

Pharmacists' Objections

What a purchaser and pharmacist-handler of a branded generic gets, Mr. Stetler added, is greater quality assurance and protection against liability.

Such claims are disputed by the legislative critics, who say their research has disclosed no difference in general quality between generic and trade-named drugs. Nor, they said, have they come up with any case in which a generic manufacturer has been sued for a flaw in his product.

Other objections to the new law were raised in an interview by Sal J. Rubino, executive director of the Pharmacists Society of the State of New York, representing about 3,500 of the 12,000 druggists in the state.

He said: "Does the consumer have the right to override—to select a trade name if he or she wants? No. If a pharmacist doesn't stock the generic, what is he going to do, send the customer elsewhere? Do I have to duplicate my entire stock?"

Assemblyman Strelzin at the Jan. 12 hearing in Albany, was equally firm. "I serve warning to the drug companies and to the heavy-handed Pharmaceutical Manufacturers Association that we intend to play hard ball," he said. He added that as long as he was consumer chairman, "attempts to weaken the impact of our law on the consumer will be exposed and resisted."

THE NEW YORK TIMES

FEBUARY 24, 1978.

Defendant's Exhibit 6 (Inwood)

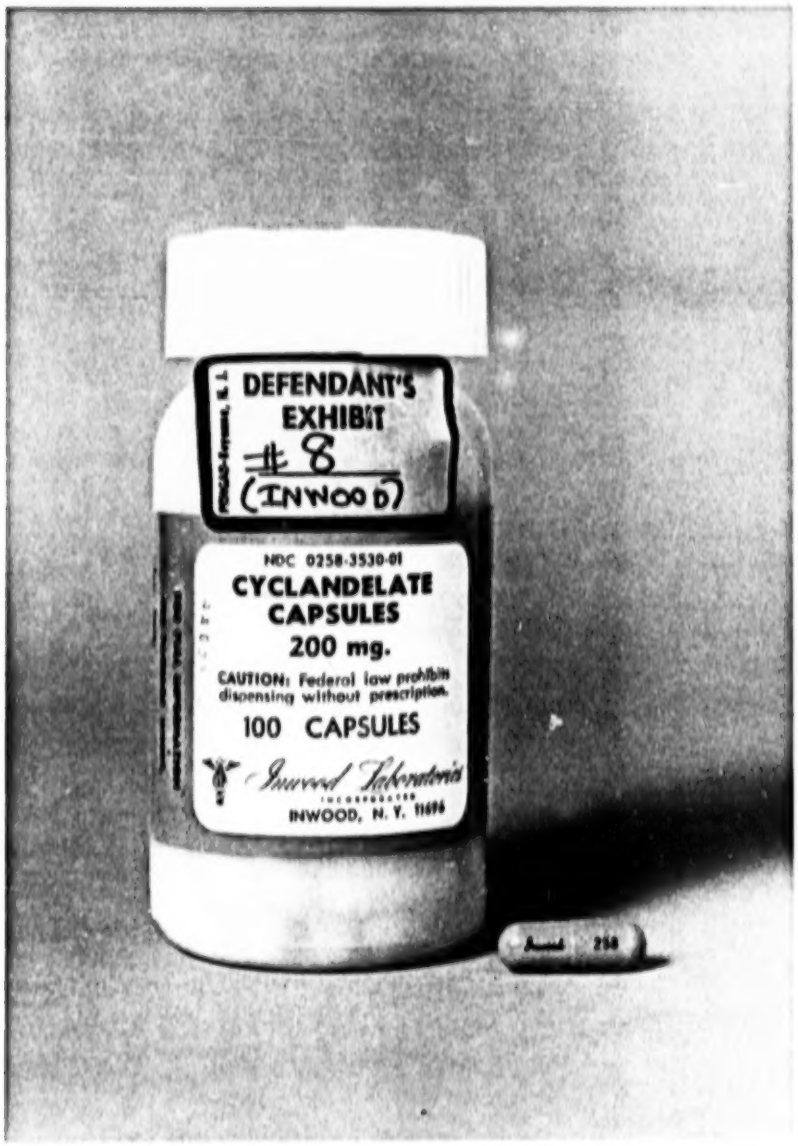
SMITH KLINE & FRENCH - Approved Drugs Actually Manufactured by Small

SK-Dexamethasone Tablets 0.5,0.75, 1.5 mg	Philips Roxane Labs
SK-Quinidine Sulfate Tablets 200 mg	"
SK-APAP with Codeine Tablets 325 mg/15,30,60 mg	"
SK-Triamcinolene Tablets 2,4 mg ("Aristocort" Lederle) ("Kenacort" Squibb)	"
SK-Prednisone Tablets 5 mg	"

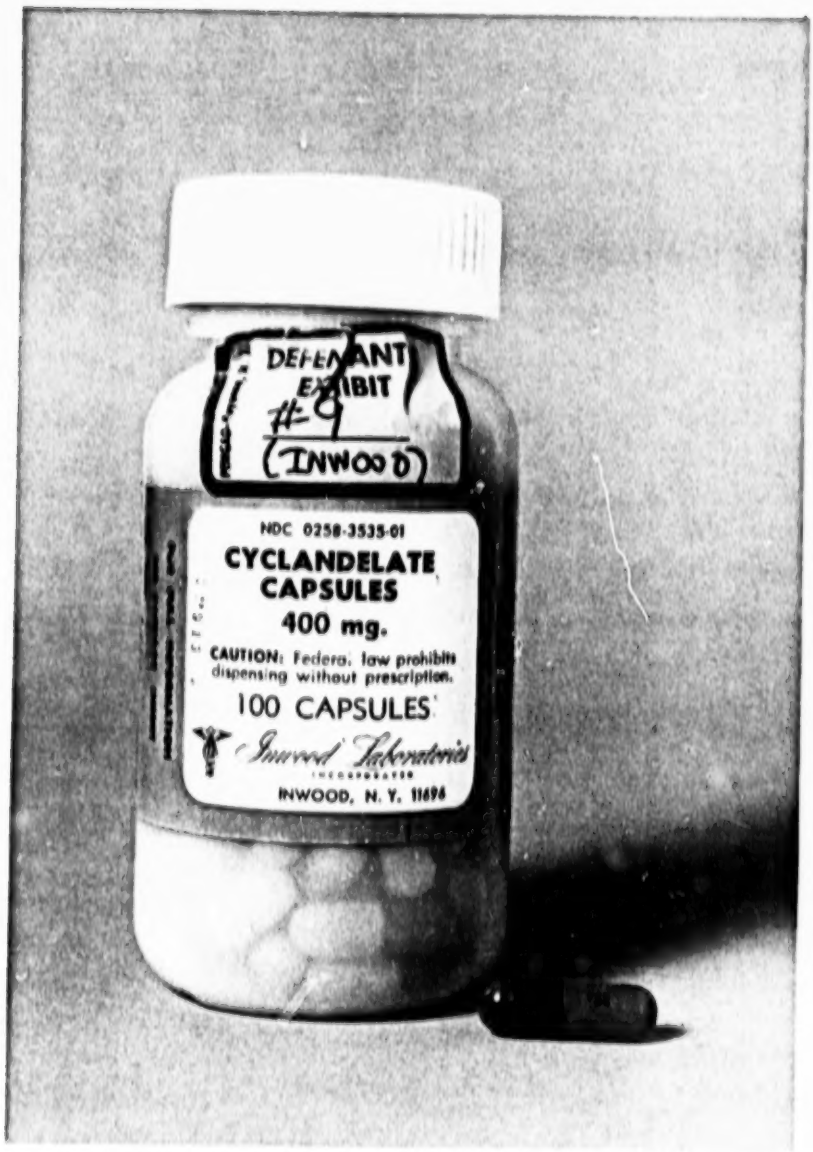
828a-830a

Defendant's Exhibit 6 (Inwood)

DEFENDANT'S EXHIBIT 8 (INWOOD)



DEFENDANT'S EXHIBIT 9 (INWOOD)



DEFENDANT'S EXHIBIT 11 (INWOOD)

State of New Jersey
Purchase Bureau
Trenton, New Jersey

CUSTOMER UNDERSTANDS ORDER IS SUBJECT TO ACCEPTANCE BY IVES AT ITS HOME OFFICE AND IF ACCEPTED, SHIPMENT WILL BE MADE WITHOUT FURTHER CONFIRMATION.

[X] QUOTATION REQUEST

THIS IS A REQUEST FOR QUOTATION. IT IS NOT AN ORDER.

REPRESENTATIVE'S INSTRUCTIONS FOR PREPARATION: PREPARE FORM WITH BALLPOINT PEN AND PRESS FIRMLY ON HARD SURFACE. FORWARD ALL COPIES TO - QUOTATIONS DEPT., IVES LABORATORIES INC., 685 THIRD AVE., NEW YORK, N.Y. 10017

DATE	CUSTOMER ORDER NO.	CUSTOMER CLASS	DEA REGISTRATION NO.	TERRITORY NUMBER	SERVICING BRANCH
5/26/77	4004		77-5-26-02	1601	Secaucus

COMPLETE COMPETITIVE INFORMATION BELOW. FORM WILL BE RETURNED IF THIS SECTION IS NOT COMPLETED.

SHOW IVES PACKAGE, QUANTITY, AND PRICE REQUIRED OPPOSITE APPLICABLE COMPETITIVE INFORMATION.

COMPETITOR PRODUCT	Quantity	SIZE	UNIT PRICE	NDC	Quantity	DESCRIPTION	SIZE	UNIT PRICE	Quotation Dept. Use
				4152-1		Isor Titradose 5mg	100	3.65	
				4152-3		Isor Titradose 5mg	1000	34.18	
				4124-4		Cyclo 200mg	1000	65.38	

REPRESENTATIVE'S COMMENTS:
(ATTACH ALL AVAILABLE DOCUMENTS SUPPORTING COMPETITIVE INFORMATION LISTED ABOVE. STATE SOURCE OF INFORMATION IF NO DOCUMENTS AVAILABLE).

EXTEND TO N/ CLASS 17

DEFENDANT'S EXHIBIT 11 INWOOD

REPRESENTATIVE'S SIGNATURE AND DATE

QUOTATIONS UNIT COMMENTS:

Contract period: 7/1/77 - 6/30/78
Terms: 2% 10 days; Net 30 days

IF FIRST ORDER IS NOT RECEIVED WITHIN 90 DAYS OF APPROVAL DATE, THIS 997 IS VOID.

QUOTATIONS DEPT. APPROVAL SIGNATURE AND DATE
Mario Moschitta 5/26/77

BRANCH COMMENTS:

DATE OF FIRST ORDER:

AMOUNT OF FIRST ORDER:

(Branch: Enter information above and return green copy to Quot. Dept.)

IVES LABORATORIES

997-E(10/75)

QUOTATIONS DEPT. COPY

Defendant's Exhibit 11 (Inwood)

...W JERSEY
...MENT OF THE TREASURY DG
...N OF PURCHASE AND PROPERTY

...RCHASE BUREAU
...VERTISED BID PROPOSAL

PURCHASE ORDER DATE	TERMS	PURCHASE ORDER NO	ACCOUNT NO
CONTRACT NO	WAIVER NO / CODE	REQUISITION NO	CONTROL NO

COMMODITY CLASSIFICATION: Various General Drugs (X-287)

DATE OF PROPOSAL: MAY 12 1977

FISCAL YEAR: 1979

...S NAME AND ADDRESS (CORRECT ANY CHANGE IN ADDRESS AND ADD ZIP CODE)

Ives Laboratories Inc
Sub American Home Prod
685 Third Avenue
New York, NY 10017

THIS BID PROPOSAL WILL BE PUBLICLY OPENED AND READ AT 2:00 P.M. ON

DATE OF BID OPENING: JUN - 6 1977

THIS PROPOSAL MUST BE RETURNED IN THE SELF ADDRESSED ENCLOSED ENVELOPE AT OR BEFORE 2:00 P.M. ON ABOVE DATE TO N.J. STATE PURCHASE BUREAU 4TH FLOOR STATE HOUSE TRENTON N.J. PROPOSALS WILL NOT BE ACCEPTED AFTER ABOVE TIME AND DATE

ADDRESS ALL INQUIRIES AND CORRESPONDENCE TO

Mr. Wagner BUYER
PURCHASE BUREAU STATE HOUSE TRENTON N.J. 08625

...TO:

Various State Agencies

BILL TO:

Various State Agencies

(Proposal to include delivery of following items F.O.B. DESTINATION.)

GENERAL INFORMATION

...ODITY CLASSIFICATION: Various General Drugs

CONTRACT PERIOD: From July 1, 1977 To June 30, 1978

...ted Amount Contract: $ 750,000.00

Amount of Bid Deposit: $ none

Amount of Performance Bond to Successful Contractor(s): $ none

...llowing paragraphs of the attached terms and conditions do not apply.

...KS: NOTE: 1. All vendors not returning bids or indicating desire to receive future proposals will be removed from vendor's list.

When inserting price bidder must insert brand and product number, leave contract No. Space Blank

All prices quoted shall be firm and not subject to increase during the period of the contract.

NOTE: Performance Bond is not required. However, the State will pay invoices only when the contractor has complied with all terms and conditions of the contract.

Notice - Bid deposit is not required on this proposal. Failure to hold price(s) for the period indicated on your bid, may result in suspension or debarment.

Page 1 of 60

...CTIONS TO AND INFORMATION TO BE COMPLETED BY VENDOR: This is an ADVERTISED BID. Note details and conditions concerning Annual Bid Bond, ... Check described below. Read all instructions, terms and conditions on front and back of proposal and fill in completely. Each price sheet attached must ...pletely filled in and returned with proposal. Bidder must sign proposal and each price sheet in ink. Failure to return all parts of this proposal may result ... of this bid.

...ONE BLOCK
...ON BID
...ON BID
...ATTACHED
...CHECK
...ATTACHED

This is an Advertised Bid. Bid must be accompanied by a certified check drawn to the order of the Treasurer of the State of New Jersey for not less than 10% of the amount of the bid unless otherwise specified in Additional Terms and Conditions. An Individual Bid Bond or Annual Blanket Bid Bond issued by an insurance or surety company authorized to do business in the State of New Jersey, and acceptable to the Director, Division of Purchase and Property will be accepted as meeting this requirement.

This Annual Blanket Bid Bond is to cover the period ending June 30th next and must be on file on or before the date and time of bid opening. Annual Blanket Bid Bond must be in a sufficient amount to cover the required deposit of all bids under consideration. The successful bidder(s) will be required to submit a Performance Bond for 10% of the amount of any order(s) and/or contract(s) placed as a result of this proposal, unless otherwise specified in Additional Terms and Conditions.

...DISCOUNT TERMS: 2% 10 days; Net 30 days
...DISCOUNT TERMS OF LESS THAN ONE PER CENT OR DISCOUNT PERIODS OF ...THAN THIRTY (30) DAYS WILL NOT BE CONSIDERED AS FACTORS IN AWARD ...CONTRACT

3. PRICES QUOTED FIRM TO ISSUE PURCHASE ORDER UNTIL FOLLOWING DATE

4. TELEPHONE NUMBER: 212/986-1000

...ERY UNLESS OTHER ...CORD IN THE PROPOSAL ...: 10 DAYS / WEEKS AFTER RECEIPT OF ORDER

2. BIDDER'S FEDERAL EMPLOYER'S IDENTIFICATION NUMBER: 13-1998397

...ATURE OF BIDDER (AND MUST BE SIGNED): John Kashickey

7. TITLE: Asst. Sales Manager

DATE: 5/26/77

ADDITIONAL TERMS AND CONDITIONS OF THIS PROPOSAL ON REVERSE SIDE

ITEM #	DESCRIPTION	SIZE	BRAND	PRODUCTS NO.	STANDARD PACKAGING	PRICE	VENDOR	CONTRACT #
421	Conjugated Estrogens Tablet USP	0.625 mg			100			
					1000			
422	Conjugated Estrogens Tablet USP	1.25 mg			100			
					1000			
422A	Cyclandelate Capsules Blue Color	1000			1000			
			CYCLOSPASMOL	82-4124-4	10 x 1000	65.38/M	Ives Laboratories Inc	
423	Desipramine HCL	25 mg			1000			
		50 mg			1000			
424	Dexamethasone	0.75 mg			50			
					250			
426	Dicumarol Tablets	50 mg			1000			
427	Dicumarol Tablets	100 mg			100			
428	Diethylstilbestrol E.C.	1 mg.			1000			
		5 mg			1000			
429	Digitoxin Tablets	0.1 mg			1000			
430	Digitoxin Tablets	0.2 mg			1000			

835a Defendant's Exhibit 11 (Inwood)

Defendant's Exhibit 11 (Inwood)

SHIP TO:

State of New Jersey

Purchase Bureau

Trenton, New Jersey

☐ **QUOTATION ORDER**

CUSTOMER UNDERSTANDS ORDER IS SUBJECT TO ACCEPTANCE BY IVES AT ITS HOME OFFICE AND IF ACCEPTED, SHIPMENT WILL BE MADE WITHOUT FURTHER CONFIRMATION.

☒ **QUOTATION REQUEST**

THIS IS A REQUEST FOR QUOTATION. IT IS NOT AN ORDER.

-935e-

REPRESENTATIVE'S INSTRUCTIONS FOR PREPARATION: PREPARE FORM WITH BALLPOINT PEN AND PRESS FIRMLY ON HARD SURFACE. FORWARD ALL COPIES TO - QUOTATIONS DEPT., IVES LABORATORIES INC., 685 THIRD AVE., NEW YORK, N.Y. 10017.

DATE	CUSTOMER ORDER NO.	CUSTOMER CLASS	DEA REGISTRATION NO.	TERRITORY NUMBER	SERVICING BRANCH
5/10/76				11.01	Secaucus

COMPLETE COMPETITIVE INFORMATION BELOW. FORM WILL BE RETURNED IF THIS SECTION IS NOT COMPLETED.

SHOW IVES PACKAGE, QUANTITY, AND PRICE REQUIRED OPPOSITE APPLICABLE COMPETITIVE INFORMATION.

COMPETITOR PRODUCT	Quantity	SIZE	UNIT PRICE	NDC	Quantity	DESCRIPTION	SIZE	UNIT PRICE	QUOTATIONS DEPT. USE
				4124-4		Cyclo	1000	65.38	
				4131-1		Isor 5mg Oral	100	3.48	
				4131-4		Isor 5mg Oral	1000	32.55	

REPRESENTATIVE'S COMMENTS:

ATTACH ALL AVAILABLE DOCUMENTS SUPPORTING COMPETITIVE INFORMATION LISTED ABOVE. STATE SOURCE OF INFORMATION IF DOCUMENTS AVAILABLE).

REPRESENTATIVE'S SIGNATURE AND DATE

QUOTATIONS UNIT COMMENTS:

Terms: 2% 10 days; Net 30 days
Contract period: 7/1/76 - 6/30/77

IF FIRST ORDER IS NOT RECEIVED WITHIN 30 DAYS OF APPROVAL DATE, THIS 997 IS VOID.

QUOTATIONS DEPT. APPROVAL SIGNATURE AND DATE

Mario Moschitta 5/10/76

BRANCH COMMENTS:

DATE OF FIRST ORDER: _____

AMOUNT OF FIRST ORDER: _____

(Branch: Enter information above and return green copy to Quot. Dept.).

IVES LABORATORIES

(10/75)

QUOTATIONS DEPT COPY

Defendant's Exhibit 11 (Inwood)

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY MC
DIVISION OF PURCHASE AND PROPERTY

PURCHASE BUREAU ADVERTISED BID PROPOSAL

PURCHASE ORDER DATE	TERM	PURCHASE ORDER NO	ACCOUNT NO
	-936e-		

CONTRACT NO	WAIVER NO	CODE	REQUISITION NO	CONTROL NO

COMMODITY CLASSIFICATION	DATE OF PROPOSAL	FISCAL YEAR
VARIOUS GENERAL DRUGS (X96)	APR 27 1976	1977

BIDDER'S NAME AND ADDRESS. (CORRECT ANY CHANGE IN ADDRESS AND ADD ZIP CODE)

Ives Laboratories Inc
Sub.American Home Prod
685 Third Ave
New York, NY 10017

THIS BID PROPOSAL WILL BE PUBLICLY OPENED AND READ AT 2:00 P.M. ON DATE OF BID OPENING MAY 17 1976

THIS PROPOSAL MUST BE RETURNED IN THE SELF ADDRESSED ENCLOSED ENVELOPE BEFORE 2:00 P.M. ON ABOVE DATE TO N.J. STATE PURCHASE BUREAU, 4TH FLOOR STATE HOUSE TRENTON N.J. PROPOSALS WILL NOT BE ACCEPTED AFTER ABOVE TIME AND DATE

ADDRESS ALL INQUIRIES AND CORRESPONDENCE TO

Mr. Wagner BUYER
PURCHASE BUREAU STATE HOUSE TRENTON N.J. 08625

SHIP TO:

VARIOUS STATE AGENCIES

BILL TO:

VARIOUS STATE AGENCIES

(Proposal to include delivery of following items F.O.B. DESTINATION.)

GENERAL INFORMATION

COMMODITY CLASSIFICATION	CONTRACT PERIOD:	
VARIOUS GENERAL DRUGS		From July 1, 1976 To June 30, 1977

Estimated Amount of the Contract:	Amount of Bid Deposit:	Amount of Performance Bond to Successful Contractor(s):
$ 750,000.00	$ 1,000.00	$ 10% of Awa

The following paragraphs of the attached terms and conditions do not apply.

REMARKS: NOTE: 1. All vendors not returning bids or indicating desire to receive future proposals will be removed from vendor's list.

When inserting price bidder must insert brand and product number, leave contract No. Space Blank

All prices quoted shall be firm and not subject to increase during the period of the contract.

INSTRUCTIONS TO AND INFORMATION TO BE COMPLETED BY VENDOR: This is an ADVERTISED BID. Note details and conditions concerning Annual Bid Bond. Certified Check described below. Read all instructions, terms and conditions on front and back of proposal and fill in completely. Each price sheet attached must be completely filled in and returned with proposal. Bidder must sign proposal and each price sheet in ink. Failure to return all parts of this proposal may result in rejection of this bid.

CHECK ONE BLOCK
- [ ] ANNUAL BID BOND ON FILE
- [ ] INDIVIDUAL BID BOND ATTACHED
- [ ] CERTIFIED CHECK ATTACHED

This is an Advertised Bid. Bid must be accompanied by a certified check drawn to the order of the Treasurer of the State of New Jersey for not less than 10% of the amount of the bid unless otherwise specified in Additional Terms and Conditions. An Individual Bid Bond or Annual Blanket Bid Bond issued by an insurance or surety company authorized to do business in the State of New Jersey, and acceptable to the Director, Division of Purchase and Property will be accepted as meeting this requirement.

This Annual Blanket Bid Bond is to cover the period ending June 30th and must be on file on or before the date and time of bid opening. Annual Blanket Bid Bond must be in a sufficient amount to cover the required deposit of all bids under consideration. The successful bidder(s) will be required to submit a Performance Bond for 10% of the amount of order(s) and/or contract(s) placed as a result of this proposal, unless otherwise specified in Additional Terms and Conditions.

1. CASH DISCOUNT TERMS: 2% 10 days; Net 30 days
CASH DISCOUNT TERMS OF LESS THAN ONE PER CENT OR DISCOUNT PERIODS OF LESS THAN THIRTY (30) DAYS WILL NOT BE CONSIDERED AS FACTORS IN AWARD OF CONTRACT

3. PRICES QUOTED FIRM TO ISSUE PURCHASE ORDER UNTIL FOLLOWING DATE

4. TELEPHONE NUMBER: 212/986-1000

5. DELIVERY: UNLESS OTHERWISE SPECIFIED IN THE PROPOSAL CAN BE MADE: 10 DAYS WEEKS AFTER RECEIPT OF ORDER

2. BIDDER'S FEDERAL EMPLOYER'S IDENTIFICATION NUMBER: 13-1998397

6. SIGNATURE OF BIDDER (NO MUST BE SIGNED): John Kashickey

7. TITLE: Asst. Sales Manager

DATE: 4/29/

ADDITIONAL TERMS AND CONDITIONS OF THIS PROPOSAL ON REVERSE SIDE

ITEM NO.	DESCRIPTION	SIZE	BRAND	PRODUCT NO.	STANDARD PACKAGING	PRICE	VENDOR	CON. TRACT NO.
422A	Cyclandelate Capsules Blue Color —	1000	Cyclospasmol	82-4124-4	1000 10 x 1000	65.38/M	Ives Laborator	
423	Desipramine HCL	25 mg. 50 mg.			1000 1000			
424	Dexamethasone	0.75 mg.			50 250			
426	Dicumarol Tablets	50 mg.			1000			
427	" "	100 mg.			100 1000			
428	Diethylstilbestrol E.C.	1 mg. 5 mg.			1000			
429	Digitoxin Tablets	0.1 mg.			1000			
430	" "	0.2 mg.			1000			
431	Digoxin "	0.25 mg.			1000			
431A	Digoxin Tablets	UNIT DOSE			10 strips of 10/bx			
432	" "	0.5 mg.			1000			
432A	Digoxin Tablets (BIDDER SPECIFY HARD DRY FILLED OR SOFT LIQUID FILLED GELATIN CAPSULE)	UNIT DOSE						
433	Dioctyl Sodium Sulfosuccinate Capsules (BIDDER SPECIFY HARD DRY FILLED OR SOFT LIQUID FILLED GELATIN CAPSULE)	100 mg.			250 1000			
434	Dioctyl Sodium Sulfosuccinate Capsules	250 mg.			250 1000			
435	Doxepin HCl Capsules	10 MG 25 Mg. 50 mg			1000 x1000 10 x1000 25 x1000 50 x1000 1000 10x1000 25x1000 50x1000			

838a
Defendant's Exhibit 11 (Inwood)
-937e-

EXHIBIT C OF STEMPEL AFFIDAVIT

NATIONAL BRAND DRUGS AND GENERIC DRUGS HAVING IDENTICAL APPEARANCES

NAT BRAND DRUGS	GENERIC DRUGS
1	1A
2	2A 2B 2C
3	3A 3B
4	4A 4B
5	5A 5B 5C
6	6A 6B
7	7A
8	8A
9	9A 9B
10	10A
11	11A
12	12A
13	13A 13B 13C 13D 13E
14	14A
15	15A
16	16A
17	17A 17B
18	18A 18B
19	19A
20	20A
21	21A 21B
22	22A
23	23A
24	24A
25	25A
26	26A 26B 26C 26D
27	27A 27B
28	28A 28B
29	29A 29B 29C
30	30A
31	31A 31B
32	32A
33	33A
34	34A
35	35A
36	36A 36B 36C
37	37A 37B 37C
38	38A
39	39A
40	40A 40B
41	41A
42	42A
43	43A
44	44A 44B
45	45A 45B
46	46A 46B
47	47A 47B
48	48A
49	49A
50	50A
51	51A
52	52A
53	53A
54	54A 54B
55	55A
56	56A
57	57A 57B
58	58A
59	59A
60	60A
61	61A 61B 61C
62	62A
63	63A 63B 63C 63D
64	64A 64B
65	65A
66	66A 66B 66C
67	67A
68	68A
69	69A
70	70A
71	71A 71B
72	72A
73	73A 73B 73C
74	74A
75	75A
76	76A
77	77A
78	78A
79	79A
80	80A
81	81A
82	82A
83	83A
84	84A
85	85A
86	86A
87	87A
88	88A
89	89A
90	90A

DEFENDANT'S EXHIBIT 4 (PREMO)

839a

DEFENDANT'S EXHIBIT 5 (PREMO)

KEY TO EXHIBIT C OF STEMPEL AFFIDAVIT

On Exhibit C each national brand product is designated by a plain Arabic number, for example, "1". Each equivalent generic drug of that national brand product is designated by the same number but a capital letter is also included, the first generic equivalent being, for example, "1A", the next, if any, "1B", and so on.

To correlate the products depicted on Exhibit C with the names of the drugs and the names of the national brand manufacturers and generic drug suppliers (manufacturers and distributors), the following listing is furnished. In the listing, the national brand name of the drug is set forth; then the name of the national brand manufacturer thereof is listed after the number which designates the national brand product on the exhibit, and the name of the generic drug supplier is listed after the number and capital letter which designate the generic product on the exhibit.

Actifed

1. Burroughs Wellcome Co.
1A. Steri-Med, Inc.

Allbee with C

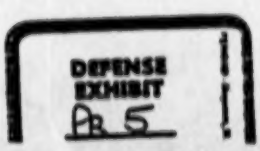
2. A. H. Robins Company
2A. Vitafore Products Co., Inc.
2B. Gen King
2C. Blue Cross Products, Inc.

Antivert 12.5 mg.

3. Roerig
3A. Rugby Laboratories, Inc.
3B. Steri-Med, Inc.

Antivert 25 mg.

4. Roerig
4A. Rugby Laboratories, Inc.
4B. Zenith Laboratories, Inc.



Defendant's Exhibit 5 (Premo)

Apresoline 25 mg.

5. Ciba Pharmaceutical Company
5A. Zenith Laboratories, Inc.
5B. West-Ward, Inc.
5C. Rogers Wholesalers, Inc.

Azo Gantrisin

6. Roche Laboratories
6A. Rugby Laboratories, Inc.
6B. West-Ward, Inc.

Bellergal

7. Dorsey Laboratories
7A. Spencer-Mead, Inc.

Roniacol Timespan

8. Roche Laboratories
8A. Bolar Pharmaceutical Co.

Benedryl

9. Parke, Davis & Company
9A. Zenith Laboratories, Inc.
9B. Danbury Pharmaceuticals

Benemid

10. Merck Sharp & Dohme
10A. Three P Products Corp.

Bentyl

11. Merrell-National Laboratories
11A. Bolar Pharmaceutical Co.

Cafergot

12. Sandoz Pharmaceuticals
12A. Richlyn Laboratories, Inc.

Chlor-Trimeton 4 mg.

13. Schering Corporation
13A. American Pharmaceutical Co.
13B. Generic Pharmaceutical Corp.
13C. Wolins Pharmacal Company
13D. Barr Laboratories, Inc.
13E. Superon Drugs

Chlor-Trimeton 8 mg.

14. Schering Corporation
14A. Panray Div., Ormont Drug & Chemical Co.

Defendant's Exhibit 5 (Premo)

Chlor-Trimeton 12 mg.

15. Schering Corporation
15A. Rogers Wholesalers, Inc.

Combid

16. Smith Kline & French Laboratories
16A. Rugby Laboratories, Inc.

Cyclospasmol 200 mg.

17. Ives Laboratories, Inc.
17A. Premo Pharmaceutical Laboratories, Inc.
17B. MD Pharmaceutical Company, Inc.

Cyclosopasmol 400 mg.

18. Ives Laboratories, Inc.
18A. Premo Pharmaceutical Laboratories, Inc.
18B. Inwood Laboratories, Inc.

Decadron

19. Merck, Sharp & Dohme
19A. Three P Products Corp.

Dimetane

20. A. H. Robins Company
20A. Danbury Pharmaceuticals

Dimetapp Extentabs

21. A. H. Robins Company
21A. Bioline Laboratories, Inc.
21B. Premo Pharmaceutical Laboratories, Inc.

Diuril 250 mg.

22. Merck Sharp & Dohme
22A. Steri-Med, Inc.

Diuril 500 mg.

23. Merck Sharp & Dohme
23A. Steri-Med, Inc.

Donnatal

24. A. H. Robins Company
24A. Steri-Med, Inc.

Dramamine

25. Searle Laboratories
25A. West-Ward, Inc.

Defendant's Exhibit 5 (Premo)

Dulcolax

26. Boehringer Ingelheim Ltd.
26A. Gen King
26B. American Pharmaceutical Co.
26C. Bioline Laboratories, Inc.
26D. Columbia Medical Company

Elavil 10 mg.

27. Merck Sharp & Dohme
27A. Biocraft Labs., Inc.
27B. Steri-Med, Inc.

Elavil 25 mg.

28. Merck Sharp & Dohme
28A. Biocraft Labs., Inc.
28C. Steri-Med, Inc.

Elavil 50 mg.

29. Merck Sharp & Dohme
29A. Biocraft Labs., Inc.
29B. Rugby Laboratories, Inc.
29C. Steri-Med, Inc.

Ecotrin

30. Smith Kline & French Laboratories
30A. Spencer-Mead, Inc.

Feosol

31. Smith Kline & French Laboratories
31A. Premo Pharmaceutical Laboratories, Inc.
31B. Zenith Laboratories, Inc.

Fergon

32. Breon Laboratories, Inc.
32A. Blue Cross Products, Inc.

Furadantin 50 mg.

33. Eaton Laboratories, Inc.
33A. Zenith Laboratories, Inc.

Furadantin 100 mg.

34. Eaton Laboratories, Inc.
34A. Steri-Med, Inc.

Gantrisin

35. Roche Laboratories
35A. Heather Drug Co.

Defendant's Exhibit 5 (Premo)

Hydrodiuril 25 mg.

36. Merck Sharp & Dohme
36A. Bolar Pharmaceutical Co.
36B. Henry Schein, Inc.
36C. J. Dans Labs.

Hydrodiuril 50 mg.

37. Merck Sharp & Dohme
37A. Inwood Laboratories, Inc.
37B. Gen King
37C. Bioline Laboratories, Inc.

Hydropres 25 mg.

38. Merck Sharp & Dohme
38A. Danbury Pharmaceuticals

Hydropres 50 mg.

39. Merck Sharp & Dohme
39A. Zenith Laboratories, Inc.

Isordil 5 mg.

40. Ives Laboratories, Inc.
40A. Three P Products Corp.
40B. Steri-Med, Inc.

Isordil 5 mg. Sub-Lingual

41. Ives Laboratories, Inc.
41A. Spencer-Mead, Inc.

Isordil 10 mg.

42. Ives Laboratories, Inc.
42A. Steri-Med, Inc.

Isordil Tembids 40 mg.

43. Ives Laboratories, Inc.
43A. Three P Products Corp.

Lanoxin

44. Burroughs Wellcome Co.
44A. Steri-Med, Inc.
44B. Zenith Laboratories, Inc.

Larotid

45. Roche Laboratories
45A. Three P Products Corp.
45B. Biocraft Labs., Inc.

Defendant's Exhibit 5 (Premo)

Macrodantin 50 mg.

46. Eaton Laboratories, Inc.
46A. Rugby Laboratories, Inc.
46B. Bolar Pharmaceutical Co.

Macrodantin 100 mg.

47. Eaton Laboratories, Inc.
47A. Rugby Laboratories, Inc.
47B. Bolar Pharmaceutical Co.

Mandelamine

48. Warner/Chilcott
48A. Henry Schein, Inc.

Marax

49. Roerig
49A. Three P Products Corp.

Miltrate

50. Wallace Laboratories
50A. Spencer-Mead, Inc.

Neomycin Sulfate

51. Eli Lilly and Company
51A. Steri-Med, Inc.

Nitro-Bid 2.5 mg.

52. Marion Laboratories, Inc.
52A. Henry Schein, Inc.

Nitro-Bid 6.5 mg.

53. Marion Laboratories, Inc.
53A. Three P Products Corp.

Norgesic

54. Riker Laboratories, Inc.
54A. Inwood Laboratories, Inc.
54B. Zenith Laboratories, Inc.

Orinase

55. The Upjohn Company
55A. Premo Pharmaceutical Laboratories, Inc.

Ornade

56. Smith Kline & French Laboratories
56A. Spencer-Mead, Inc.

Defendant's Exhibit 5 (Premo)

Pavabid

57. Marion Laboratories, Inc.
57A. Henry Schein, Inc.
57B. Halsey Drug Co.

Peri-Colace

58. Mead Johnson & Company
58A. Bioline Laboratories, Inc.

Peritrate 20 mg.

59. Warner/Chilcott
59A. Bioline Laboratories, Inc.

Peritrate 10 mg.

60. Warner/Chilcott
60A. Halsey Drug Co.

Polycillin

61. Bristol Laboratories
61A. Bioline Laboratories, Inc.
61B. Pierrel American, Inc.
61C. Biocraft Labs., Inc.

Premarin .625 mg.

62. Ayerst Laboratories
62A. Alliance Laboratories, Inc.

Premarin 1.25 mg.

63. Ayerst Laboratories
63A. Rugby Laboratories, Inc.
63B. Invenex Pharmaceuticals
63C. Three P Products Corp.
63D. Strong, Cobb, Arner, Inc.

Pronestyl 250 mg.

64. E. R. Squibb & Sons
64A. Rugby Laboratories, Inc.
64B. Aberdeen Pharmacal Corp.

Pronestyl 500 mg.

65. E. R. Squibb & Sons
65A. Zenith Laboratories, Inc.

Pro-Banthine

66. Searle & Co.
66A. Lederle Laboratories
66B. Three P Products Corp.
66C. Mylan Pharm., Inc.

Defendant's Exhibit 5 (Premo)

Pyribenzamine

67. Ciba Pharmaceutical Company
67A. Premo Pharmaceutical Laboratories, Inc.

Pyridium

68. Warner/Chilcott
68A. Premo Pharmaceutical Laboratories, Inc.

Quibron

69. Mead Johnson & Company
69A. Rugby Laboratories, Inc.

Raudixin 50 mg.

70. E. R. Squibb & Sons
70A. Richlyn Laboratories, Inc.

Robaxin

71. A. H. Robins Company
71A. Barr Laboratories, Inc.
71B. Zenith Laboratories, Inc.

Senekot

72. The Purdue Frederick Company
72A. Spencer-Mead, Inc.

Ser-Ap-Es

73. Ciba Pharmaceutical Company
73A. Henry Schein, Inc.
73B. Zenith Laboratories, Inc.
73C. Spencer-Mead, Inc.

Serpasil

74. Ciba Pharmaceutical Company
74A. Premo Pharmaceutical Laboratories, Inc.

Theragran

75. E. R. Squibb & Sons
75A. Halsey Drug Co.

Sinutab

76. Warner/Chilcott
76A. Rugby Laboratories, Inc.

Tedral

77. Warner/Chilcott
77A. Steri-Med, Inc.

Defendant's Exhibit 5 (Premo)

Teldrin 12 mg.

78. Smith Kline & French Laboratories
78A. Spartan

Teldrin 8 mg.

79. Smith Kline & French Laboratories
79A. Spartan

Temaril

80. Smith Kline & French Laboratories
80A. Rogers Wholesalers, Inc.

Terramycin

81. Pfizer Laboratories
81A. Pierrel American, Inc.

Tetrex 250 mg.

82. Bristol Laboratories
82A. Rogers Wholesalers, Inc.

Tetrex 500 mg.

83. Bristol Laboratories
83A. Bioline Laboratories, Inc.

Thorazine

84. Smith Kline & French Laboratories
84A. The Interstate Drug Exchange, Inc.
84B. Zenith Laboratories, Inc.

Tofranil

85. Geigy Pharmaceuticals
85A. Cord Laboratories, Inc.

Triaminic

86. Dorsey Laboratories
86A. Henry Schein, Inc.

Trised

87. Webcon Pharmaceuticals
87A. Henry Schein, Inc.

Vasodilan

88. Mead Johnson & Company
88A. Premo Pharmaceutical Laboratories, Inc.

Defendant's Exhibit 5 (Premo)

Vibramycin

89. Pfizer Laboratories
89A. Three P Products Corp.

Larotid

90. Roche Laboratories
90A. Biocraft Labs., Inc.

DEFENDANT'S EXHIBIT 22 (PREMO)

-771e-

PREMO BRAND	TABLETS AND CAPSULES	NATIONAL BRAND
ALLEMOL VELVETABS		GAVISCON TABLETS
ALLOPURINOL TABLETS 100MG		ZYLOPRIM TABLETS
ALLOPURINOL TABLETS 300MG		ZYLOPRIM TABLETS
*CHLORDIAZEPOXIDE HCl CAPSULES 5MG		LIBRIUM CAPSULES
*CHLORDIAZEPOXIDE HCl CAPSULES 10MG		LIBRIUM CAPSULES
*CHLORDIAZEPOXIDE HCl CAPSULES 25MG		LIBRIUM CAPSULES
CHLORDINIUM SEALETS		LIBRAX CAPSULES
CHLORTHALIDONE TABLETS 50MG		HYGROTON TABLETS
CHLORTHALIDONE TABLETS 100MG		HYGROTON TABLETS
CHLORZOXAZONE WITH APAP TABLETS		PARAFON FORTE TABLETS
CYCLANDELATE CAPSULES 200MG		CYCLOSPASMOL CAPSULES
CYCLANDELATE CAPSULES 400MG		CYCLOSPASMOL CAPSULES
DIPYRIDAMOLE TABLETS		PERSANTINE TABLETS
DOXINE TABLETS		BENDECTINE TABLETS
DYNOHIST S.A. TABLETS		ANTIHISTAMINE/DECONGESTANT
HYDRALAZINE HCl TABLETS 25MG		APRESOLINE TABLETS
HYDRALAZINE HCl TABLETS 50MG		APRESOLINE TABLETS
HYDROXYZINE HCl TABLETS 10MG		ATARAX TABLETS
HYDROXYZINE HCl TABLETS 25MG		ATARAX TABLETS
HYDROXYZINE HCl TABLETS 50MG		ATARAX TABLETS
HY-PAM CAPSULES 25MG		VISTARIL CAPSULES
HY-PAM CAPSULES 50MG		VISTARIL CAPSULES
IMIPRAMINE HCl TABLETS 10MG		TOFRANIL TABLETS
IMIPRAMINE HCl TABLETS 25MG		TOFRANIL TABLETS
IMIPRAMINE HCl TABLETS 50MG		TOFRANIL TABLETS
INSULASE TABLETS (CHLORPROPAMIDE)		DIABINESE TABLETS
ISOXSUPRINE HCl TABLETS 10MG		VASODILAN TABLETS
ISOXSUPRINE HCl TABLETS 20MG		VASODILAN TABLETS
*MEPROGESIC TABLETS		EQUAGESIC TABLETS
MEPRO-HEX "200" TABLETS		PATHIBAMATE/MILPATH TABLETS
MEPRO-HEX "400" TABLETS		PATHIBAMATE/MILPATH TABLETS
NYSTATIN ORAL TABLETS		MYCOSTATIN ORAL TABLETS
NYSTATIN VAGINAL TABLETS		MYCOSTATIN VAGINAL TABLETS
PHENYLBUTAZONE ALKA CAPSULES		BUTAZOLIDIN ALKA CAPSULES
*PROPOXYPHENE COMPOUND CAPSULES 65MG		DARVON COMPOUND CAPSULES
*PROPOXYPHENE HCl CAPSULES 65MG		DARVON CAPSULES
THEOPHEDRIZINE TABLETS		MARAX TABLETS
TOLBUTAMIDE TABLETS		ORINASE TABLETS

Premo does not offer for sale the National brand products in Column II. Premo products li in Column I contain the same active ingredient.

*CIV Product - DEA Number Required

12/1/79

premo

"Pioneers in Generics"

DEFENSE EXHIBIT PB 22

Premo Pharmaceutical Laboratories, Inc.

111 LEUNING ST., SO. HACKENSACK, N.J. U.S.A. 07606 / (201) 343-5000

Defendant's Exhibit 22 (Premo)

CREAMS

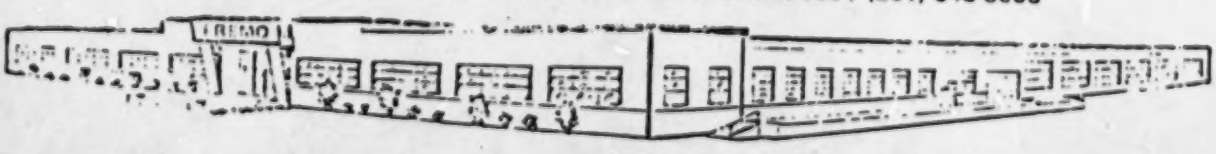
BETA-VAL CREAM 15GM.	BETAMETHASONE VALERATE CREAM
BETA-VAL CREAM 45GM.	BETAMETHASONE VALERATE CREAM
MYCO TRIACET CREAM.	MYCOLOG CREAM
MYCOSTATIN CREAM.	MYCOSTATIN CREAM
TRIACET CREAM .025%.	KENALOG AND ARISTACORT CREAM
TRIACET CREAM .1%.	KENALOG AND ARISTACORT CREAM
TRIACET CREAM .5%.	KENALOG AND ARISTACORT CREAM

Premo products are designed and manufactured for proper dispensing in accordance with all applicable State and Federal laws.

premo

"Pioneers in Generics"

Premo Pharmaceutical Laboratories, Inc.
111 LEUNING ST., SO. HACKENSACK, N.J. U.S.A. 07606 / (201) 343-5000



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JUL 23 1981
ALEXANDER L. STEVAS,
CLERK

Nos. 80-2182, 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

REPLY TO PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MARIE V. DRISCOLL
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New York, New York 10112
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Attorneys for Respondent, Ives Laboratories, Inc.

Of Counsel:

EGON E. BERG
STEVEN J. BARON

Question Presented

1. Did the Court of Appeals err in holding the petitioners, who are manufacturers and distributors of prescription drugs sold in capsules which deliberately simulated the appearance of the respondent's drug capsules, liable for contributory infringement of the plaintiff's registered trademark where there was undisputed evidence that the look-alike capsules had been illegally dispensed by pharmacists and labelled with the respondent's trademark; that a series of pharmacy shoppings in New York State showed that 29% of the prescriptions filled with the look-alike capsules are mislabelled with respondent's trademark; that the simulating of the appearance of respondent's capsules makes illegal substitution and undetected mislabelling easier; that there is no legitimate functional reason for copying the colors; and that the petitioners, in selling their capsules, among other things, emphasize that the colors of their capsules are the same as those of plaintiff?

Statement Pursuant to Supreme Court Rule 28.1

Respondent Ives Laboratories, Inc. (hereinafter "Ives") is a subsidiary of American Home Products Corporation, which also has numerous other subsidiaries.

Two petitions for certiorari, one on behalf of Inwood Laboratories, Inc. and Premo Pharmaceutical Laboratories, Inc. and one on behalf of the other defendants, have been filed. This response is filed in opposition to both petitions.

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Nos. 80-2182, 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERBY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

REPLY TO PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Statement of the Case

Ives has for many years manufactured and sold a prescription drug product known by the generic name cyclandelate. It has identified this cyclandelate by using its registered trademark CYCLOSPASMOL and by selling the drug, which is a white powder, in distinctive blue and blue/red capsules. The petitioners, and defendants below, are all manufacturers and distributors of generic cyclandelate which they sell in blue and blue/red capsules copying the appearance of the Ives' capsules. The copying was admittedly deliberate. In filling prescriptions, pharmacists have illegally substituted the look-alike generic capsules

for CYCLOSPASMOL cyclandelate and have passed off the generic look-alike for CYCLOSPASMOL by showing plaintiff's trademark on the labelling of the capsules dispensed.

Ives does not seek to enjoin the sale of the drug cyclandelate. It has brought no action against a competitor selling the product in a capsule that does not copy the appearance of Ives' capsules. Rather, it has alleged in this case that the sale of the product in look-alike capsules constitutes a false designation of origin under Section 43(a) of the Lanham Act and unfair competition under New York law. It has also charged that the defendants are liable for contributory infringement of Ives' trademark, in violation of Section 32 of the Lanham Act, 15 U.S.C. §1114.

At trial, Ives introduced substantial evidence in support of its claims under §43(a) of the Lanham Act and New York's law of unfair competition, including a survey which established that patients associate the capsule colors blue and blue/red with CYCLOSPASMOL and that 70% of those patients interviewed, when shown the defendants' look-alike capsules, misidentified them as plaintiff's product CYCLOSPASMOL.* The Court of Appeals decided that the defendants were liable for contributory trademark infringement, and thus did not reach these other claims.

From the outset, the District Court took a very narrow and restrictive view of all aspects of the applicable law. In denying Ives' Motion for Preliminary Injunction it held, on the issue of contributory infringement, that plaintiff had failed to show that the defendants "have conspired with the pharmacists or suggested that they disregard the doctors' orders." (13a) The Court noted that mislabelling

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* This represents combined misidentification for both the blue and blue/red capsules, aided and unaided.

would subject a pharmacist to criminal and civil penalties. Although acknowledging that use of the blue and blue/red capsules "may make discovery of the offense less likely" it held that this "scarcely justified holding defendants as accessories to the crime." (13a) It interpreted the law of contributory infringement as extending only to those who actively share a retailers' infringement. (13a)

Although affirming the denial of a preliminary injunction as being within the discretion of the District Court, the Court of Appeals on the first appeal, in a decision written by Judge Friendly, corrected numerous errors of law of the lower court. On the issue of contributory infringement, it first noted that the most serious act of wrongdoing by pharmacists occurs where CYCLOSPASMOL has been prescribed, but the pharmacist illegally substitutes the look-alike cyclandelate and mislabels it as CYCLOSPASMOL. A wrong characterized by Judge Friendly as "intermediate" occurs when the prescription permits substitution and the druggist fills it with defendants' product, but names it CYCLOSPASMOL, an act "clearly actionable against the druggist". (34a)

The Court of Appeals, on the first appeal, held that, while these wrongdoings may be actionable under the New York Education Law, that law does not displace the protection for competitors embodied in trademark and unfair competition law. It noted that the District Court's reading of applicable law was too narrow, and was erroneous (35a):

> "... a manufacturer or wholesaler would be liable under §32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described."

The Court also accepted as the "proper criteria" those stated in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D. Mass. 1946), aff'd 162 F.2d 280 (1 Cir. 1947), cert. denied, 332 U.S. 809 (1947) in which it was held that a manufacturer's accountability for infringement committed by its customers (64 F.Supp. at p. 989):

> "... turn(s) on the issue whether a reasonable person in the defendant's position would realize either that he himself had created a situation which afforded a temptation to or an opportunity for wrong by l'homme moyen sensuel or was dealing with a customer whom he should know would be peculiarily likely to use the defendant's product wrongfully."

Judge Friendly held that, if the District Court judge "considered a narrower view of the doctrine of contributory infringement to be warranted because mislabeling by a New York pharmacist 'would put him at risk of criminal and civil penalties and would subject him to the loss of his license' and thought that defendants would be liable for contributory infringement only if they could be held 'as accessories to the crime' he was in error." (35a) The petitioners herein have not claimed that the first decision of the Court of Appeals was erroneous.

At trial there was substantial uncontradicted evidence that pharmacists had passed off the look-alike cyclandelate capsules as Ives' CYCLOSPASMOL capsules. There were fifteen instances in which shoppings at pharmacies showed illegal substitution of the generic, with thirteen of the bottles being then labelled CYCLOSPASMOL.* It was

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* Although the defendants downplay this evidence as not being substantial, the Court of Appeals noted that "it was surprising that Ives was able to produce as many such instances as it did." (81a)

also proved that a pharmacist in Ohio had put unmarked look-alike capsules into single dosage unit packs which he then individually mislabelled CYCLOSPASMOL or CYCLANDELATE CYCLOSPAZMOL. [sic] There was also substantial evidence of the "intermediate" wrongdoing described by the Court of Appeals on the first appeal. Ives had a series of random pharmacy shoppings done at 83 pharmacies in New York State which showed that, of the 35 pharmacies dispensing the generic look-alike in filling a "substitution permissible" prescription, 29% mislabelled the product using plaintiff's CYCLOSPASMOL trademark. Contrary to the assertions in petitioner's briefs, the pharmacists were not merely making a fair descriptive use of the trademark.* Statistical evidence showed that the results of those shoppings were projectible on a statewide basis.

In addition, one of the defendants, Premo Pharmaceutical Laboratories, Inc. (hereinafter "Premo") did shoppings in 25 pharmacies and produced two instances in which the labels on generic cyclandelate wrongly showed the trademark CYCLOSPASMOL. Ives also did a survey to establish that patients associate the blue and blue/red capsule colors with CYCLOSPASMOL. In 9 of 17 instances where the patients interviewed at home produced their medicine bottles to the interviewer during the survey interviews, the bottles contained generic cyclandelate, but the labels erroneously identified the product as CYCLOSPASMOL.

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* The ten labels (which petitioners Darby Drug Co., Inc., et al. acknowledge at page 9 of their petition to be examples of mislabelling) show: CYCLOSPASMOL: Generic Cyclospasmol; Cyclospasmol (Gen); Cyclospasmol; Cyclospasmol Generic; Cyclospasmol 400 ETE(Rugby); Generic Cyclospasmol; Cyclospasmol; and Cyclospasmol.

An officer of the defendant Inwood Laboratories Incorporated (hereinafter "Inwood") acknowledged that he knew of the existence of the practice of illegal substitution. Inwood and Premo had both been defendants in other cases in which illegal substitution was proved. The defendants admitted that the duplication of color of the capsules made such illegal substitution easier, or less readily detectable. As the president of Premo stated, "it's obvious if a man is going to do something illegal like pass off counterfeit money, it's easier if he has a good imitation."

In addition to furnishing look-alikes, defendants have emphasized in their promotional materials that their cyclandelate is in blue or blue/red capsules, and have put their generic products on lists juxtaposed with lists of the branded drugs copied, including CYCLOSPASMOL. A witness for the defendants, who was employed by a generic distributor, then a defendant in another look-alike case, testified that furnishing lists of generics and brand names makes it easier for the pharmacist with larceny in his heart.

The District Court, despite this showing, held that contributory infringement had not been proved. Despite the admonition in the opinion of Judge Friendly, it again emphasized that a pharmacist guilty of illegal substitution is subject to both civil and criminal penalties under New York law. (69a) It excused the mislabelling by holding, without the benefit of testimony or evidence, that the druggists "appear not deliberately to have been attempting to pass off the generic product as Cyclospasmol but rather to have misunderstood the precise requirements of the New York Drug substitution law." (60a) The Court also noted that most pharmacists who had mislabelled informed the customer that a generic drug was being dis-

pensed. The evidence, as noted by the Court of Appeals, however, was that they informed them not as a matter of course but only because the shopper, pursuant to instructions from the designer of this survey, had specifically inquired about this after having received the drug from the pharmacist. (80a)

The Court of Appeals, in reversing this decision, held that contributory infringement had been proved (80a):

> "We believe that the district court, in considering Ives' §32 claim, erred upon remand in declining to give any weight to additional evidence offered by Ives indicating that appellees' use of identically-colored, look-alike drug capsules assisted druggists in labeling generic cyclandelate as Ives' trademarked product CYCLOSPASMOL, and that they could reasonably anticipate that the use of these capsules would have such an effect."

It noted particularly the substantial additional evidence of "intermediate" cases of contributory infringement, and characterized the pharmacy shoppings done in New York State as having been carried out in a rigorous, impartial manner. (81a) The pattern of mislabelling disclosed by those shoppings "is precisely the sort of showing which we held would be probative of plaintiff's §32 claim." (82a)

The Court held that this evidence "was clearly sufficient to establish a §32 violation" (82a):

> "By using capsules of identical color, size and shape, together with a catalog describing their appearance and listing comparative prices of CYCLOSPASMOL and generic cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally

> for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage. This amounted to a suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct. By using look-alike capsules, appellees also reduced the likelihood that patients who were given a generic substitute would bring that fact to their doctor's (or their druggist's) attention."

The Court cited several cases in which similar conduct had been enjoined, all involving prescription drugs. It noted that the District Court conclusion that the mislabelling in the pharmacy shopping was the result of mistake on the part of the pharmacists had no support in the record. No witnesses or surveys supporting the District Court's suggestion were ever introduced at trial. (83a)

The Court of Appeals also held that the appropriate relief was to enjoin use of the look-alike capsules and require that different colors be used (86a):

> "This would alert the patient to the possibility that he has been given cyclandelate when his doctor specifically prescribed CYCLOSPASMOL, as well as put him on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received. Such a change could be made by appellees without any appreciable difficulty or expense."

In this context, the nature of the product—a prescription drug sold in small, colored capsules—becomes important. The product is prescribed principally to the elderly, and

markings on the capsules are unlikely to be noticed.* In fact, generic cyclandelate capsules bearing the imprint "Premo" were passed off as CYCLOSPASMOL by one pharmacist. Thus, Judge Friendly noted, on the first appeal, that "it is significant that, given the method of sale, Ives had no way of identifying Cyclospasmol to the ultimate consumer other than by the color of the capsule and by the imprint on it, which is contended to be of dubious value." (51a)**

Judge Friendly had also held that "one would not initially suppose the color of a capsule to be functional. Unlike the chocolate in the *Warner* case, the blue and blue-and-red coatings of Ives' capsules do not contribute to their efficacy; any other colors would do as well. The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors . . . does not seem persuasive; the evidence showed that, in addition to the other primary colors, an endless number of color combinations was available to the defendants." (50a)

Substantial evidence to reinforce this holding was introduced at trial. There was uncontradicted testimony that, when chosen by Ives, the blue and blue/red colors were completely arbitrary. The colors were not a feature disclosed or claimed in the patent. There was no suggestion

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* When first sold, the defendants' blue and blue/red capsules showed no imprint at all. Even the executives of the various defendants, after having examined the capsules, were unable to identify their particular's company's drug.

** The District Court, after trial, concluded that putting warning statements on the defendants' packages, as sold to pharmacists, would not be likely to deter deliberate and fraudulent substitution by the pharmacists. (61a) On the appeal, this was not challenged by the defendants.

in the record that the colors were medically necessary or were chosen to contribute to the therapy offered by the cyclandelate contained in the capsules, nor do the capsules themselves, which are made of gelatin, contribute to the therapeutic effect. Indeed capsules are not even necessary in dispensing cyclandelate, which is also sold in tablet form.

Displays from capsule manufacturers were introduced to show the many thousands of other color combinations that could have been selected for this or any other prescription product. There was also testimony that one competitor, W.E. Hauck Inc., sells cyclandelate in a non-look-alike all red 200 mg. capsule and had done so for at least two years.

Ives also introduced uncontradicted evidence and exhibits showing that, in numerous instances, in the case of prescription drugs for both acute and long-term therapy, color duplication is not necessary; the same products, in the same dosage forms, but in numerous different colors are available. For example, the most widely prescribed vasodilator, papaverine hydrochloride, which is taken for the same therapeutic uses as cyclandelate, comes in the same dosage form but in many different colors. Numerous colors are available, even for those drugs used in treating patient anxiety. And, the evidence showed that institutions purchasing drugs make decisions based on price, not color.

Reasons for Denying Certiorari

Petitioners have put forth no considerations that would justify the granting of certiorari. Neither the decision below, nor the record, raises the exaggerated questions of free speech, monopoly, and public policy as presented in the petitions.

I.

The Court of Appeals Decision Finding Defendants Liable for Contributory Infringement Is Consistent With Other Applicable Case Law and Presents No Questions Which Should Be Reviewed by This Court.

While the petitioners urge that the Court's decision effects a radical change in the law of trademarks, in fact it is completely consistent with applicable law. Petitioners furnished the look-alike capsules, the instrument of fraud that enabled pharmacists to illegally substitute and mislabel without detection. It is well established that a defendant's accountability under this doctrine does not require active participation in the actual infringement. Rather, it depends on whether a reasonable person in the defendant's position would realize that he had created a situation which afforded a temptation to or an opportunity for wrong, *Andrew Jergens Co.* v. *Bonded Products Corp.*, 21 F.2d 419, 424 (2 Cir. 1927), cert. denied, 275 U.S. 572 (1928); *Union-Carbide Corp.* v. *Ever-Ready, Inc.*, 531 F.2d 366, 384 (7 Cir. 1976), cert. denied, 429 U.S. 830 (1976). If passing off is foreseeable or may be reasonably anticipated, then the manufacturer is liable, *Stix Products, Inc.* v. *United Merchants & Manufacturers, Inc.*, 295 F. Supp. 479, 496 (S.D.N.Y. 1968); *Stewart Paint Mfg. Co.* v. *United Hardware Distributing Co.*, 253 F.2d 568, 575 (8 Cir. 1958). The wrong lies in "designedly enabling the dealers to palm off the preparation as that of the respondent", *William R. Warner and Co.* v. *Eli Lilly & Co.*, 265 U.S. 526, 530 (1924).

This is not a situation, as urged by petitioners Inwood and Premo, in which liability was based on their truthful comparative advertising, nor did the Court so hold. The defendants did more than disclose information about their

generic cyclandelate products. Defendants sold those products in a trade dress, blue and blue/red capsules, simulating the appearance of plaintiff's capsules; they emphasized the color identity in their catalogs; and they provided lists of their products on which there were shown, in juxtaposition, the trademarks of the market innovators copied, including Ives' CYCLOSPASMOL.

Historically, it has been held that, by the use of such tactics, manufacturers created too great a temptation for illegal substitution, *Smith, Kline & French* v. *Heart Pharmaceutical Corp.*, 90 F.Supp. 976 (S.D.N.Y. 1950); *E.R. Squibb & Sons, Inc.* v. *Premo Pharmaceutical Labs, Inc.*, 195 U.S.P.Q. 545 (S.D.N.Y. 1977); *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977), aff'd on procedural grounds, 579 F.2d 786 (3 Cir. 1978). The decision of the Court of Appeals is also consistent with a recent series of cases, also involving the sale of look-alike generic drugs, in which the practice of furnishing such an instrument of deception was enjoined. Although the cases were decided under Section 43(a) of the Lanham Act, or under general theories of unfair competition, they are nonetheless directly pertinent.

In *A.H. Robins Co.* v. *Medicine Chest Corp.*, 206 U.S.P.Q. 1015, 1019 (E.D. Mo. 1980), defendants were enjoined from selling a generic drug in look-alike blue tablets. It was held, in relevant part:

> "Anyone who puts goods into the hands of dealers for sale to the public which contain the means for deceiving purchasers, and/or which can be reasonably anticipated to so deceive, is subject to an injunction against the further provision of these means to eliminate their unfair competition against the goods of another which has been or is likely to be engaged in by the dealers on this basis. Thus, defendants Inwood,

Schein, and Spencer-Mead can be held liable for putting their products into various dealers' hands, such as defendant-pharmacists, if they can reasonably anticipate that their goods may be passed off as goods of another, whether or not they conspired with the dealer or intend the substitution of the goods involved.

• • •

"By intentionally simulating the size, shape, and color of Robins' product to enable them to sell their own products; by appropriating a significant portion of Robins' registered trademark, "DIMETAPP"; by making unsupported and unverified claims of equivalency; by emphasizing the color which the parties' products have in common; and by stressing the difference in price between the parties' products, Inwood, Schein, and Spencer-Mead have created a situation in which they knew or should have anticipated that such would result in illegal substitution of their drug for that of plaintiff."

The Court of Appeals for the Third Circuit, in *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1062 (3 Cir. 1980), likewise found that the defendant's conduct in selling a look-alike prescription drug capsule was actionable since it put the maroon and white capsule, "in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product *even if the manufacturer does nothing else to encourage passing off*." (emphasis supplied) In *Boehringer-Ingelheim G.m.b.H.* v. *Premo Pharmaceutical Laboratories, Inc.* (D.N.J. Docket No. 79-0358, September 24, 1980), it was also held that defendants facilitated passing off by pharmacists "of generic dipyridamole as Persantine by copying Persantine's trade dress" (small orange tablets).

II.

The Court of Appeals Decision Does Not Involve Any Infringement of Free Speech.

Two of the six defendants petitioning for certiorari argue that the Court's finding of liability conflicts with their First Amendment right of free speech. The other four petitioners make no such argument, and it has never been raised before in this case.

While commercial speech is protected by the First Amendment, there is no obstacle to imposing liability for commercial speech that is deceptive or misleading, *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976). And, the copyright laws are enforced although they, too, may be considered to inhibit free speech, *Zacchini* v. *Scripps-Howard Broadcasting Co.*, 433 U.S. 562, 576 (1977). Under similar theories, those who copy the trademarks or the colored trade dress of an innovator may also be enjoined without violating First Amendment rights, *Dallas Cowboys Cheerleaders, Inc.* v. *Pussycat Cinema, Ltd.*, 604 F.2d 200, 206 (2 Cir. 1979):

> "Nor does any other first amendment doctrine protect defendants' infringement of plaintiff's trademark [its cheerleaders' uniform]. That defendants' movie may convey a barely discernible message does not entitle them to appropriate plaintiff's trademark in the process of conveying that message. . . ."

In any event, the First Amendment argument in the present case is completely specious, and appears to have been raised solely to capture the Court's attention in the hope that certiorari would be granted. The decision of the Court

did not, as urged by two of the six petitioners, prevent them from adequately and accurately describing their generic products to their customers. The petitioners forget that the principal wrong was their furnishing of cyclandelate in look-alike capsules. References to their colors, and to plaintiff's trademark and the price differential between plaintiff's products and those of the petitioners merely served to aggravate that principal wrong and make it more likely that illegal substitution and mislabelling would occur. Petitioners have no First Amendment right to copy the trade dress of the Ives' product. Yet that is the only conduct enjoined. Petitioners have included in the Appendix herein the Order of the District Court entered pursuant to the mandate of the Court of Appeals. The injunction covers only the sale of look-alike capsules and does not in any way restrict any commercial speech of the defendants or inhibit what they may say truthfully in their further sale of generic cyclandelate. (102a-104a)

III.

The Court of Appeals Decision, While Protecting the Colors of Plaintiff's Capsules, Does Not Thereby Create a Monopoly in the Sale of Cyclandelate.

The decision of the Court of Appeals is also not in conflict with prior decisions cited by petitioners in which it was held that colors per se were not protectable as trademarks. The cases did not involve prescription drug capsules. As Judge Friendly held on the first appeal, color is the only effective way for Ives to identify its CYCLOSPASMOL capsules to the ultimate consumer. (51a) Cases involving the coloration of ordinary consumer goods are simply not relevant, nor are the two cases involving drug products cited by the petitioners. *Norwich Pharmacal Co.*

v. *Sterling Drug, Inc.*, 271 F.2d 569 (2 Cir. 1959), cert denied, 362 U.S. 919 (1960), was effectively distinguished by Judge Friendly on the first appeal, where he pointed out that this was an over-the-counter medication where the differences in name, labelling and packaging—all seen by the ultimate consumer—were such, that it stretched credulity to imagine a purchaser confusing them, although both were soothing pink stomach remedies. (41a, 51a) And unlike the present case, there was no evidence of passing off or deception.

In *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, p. 11, this Court refused to enjoin the defendant from selling brown colored medication. In that case, the use of chocolate was required in order to make a commercially satisfactory product, i.e., to make the preparation palatable and to act as a suspending medium for the quinine ingredient. The brown color imparted to the finished product was the natural color of the chocolate. Thus, the product necessarily had to be brown. The standard applied by the Court was whether the color, as dictated by the presence of the chocolate ingredient. "serves a substantial and desirable use" and is essential to the manufacture of the product. (265 U.S. at p. 531)

Under this standard, the blue and blue/red colors are certainly not functional. As Judge Friendly noted on the first appeal, there were thousands of other colors to select from; the selection of blue and blue/red was completely arbitrary. The ingredients in the drug are white. He also held that any evidence of functionality would have to depend on the showing defendants were able to make at trial. (50a) While the District Court held that the colors were functional, the Court of Appeals held that they were not, specifically finding the defendants' proof on this point to

be "unconvincing". "Appellees have not offered *any persuasive evidence* of a legitimate reason" to sell look-alike capsules. (84a) (emphasis supplied) Petitioners urge that the appellate decision should not be upheld because, in the opinion, Judge Mansfield did not specifically state that the District Court's findings on this issue were "clearly erroneous." Since he specifically found the evidence supporting those findings unconvincing and not persuasive, this becomes a matter of semantics. In any event, the question of functionality is one of mixed fact and law, and Judge Mansfield's finding was based not only on what was in the record, but also on the fact that certain evidence had not been introduced, particularly the testimony of patients or a survey of patient attitudes (84-85a):

> "Appellees have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically-colored, look-alike cyclandelate capsules instead of capsules of a different color, size or shape, which would minimize the practice of mislabeling, illegal substitution or confusion. Their arguments that look-alike capsules reduce patient confusion or anxiety in taking medication, enable doctors to communicate with patients more easily concerning their medication, and aid in their identification of the drug in an emergency situation, are unconvincing. Although a few doctors and one pharmacist were of the view that patients receiving capsules in a size, shape or color different from the medication they usually receive may at first believe that they have the wrong drug, there was no evidence of any instances of such confusion, much less that it was widespread, or that it could not easily be cured by explaining the change to the patient, either voluntarily in accordance with accepted professional practice or in response to the patient's inquiry. . . ."

In any event, given the completely undisputed evidence that other generic drugs are sold in colors that do not duplicate the innovator—including a generic cyclandelate and a leading drug product used for the same therapeutic uses as cyclandelate—the Court of Appeals' conclusion on this issue was the only one reasonably sustainable on the record. It is also completely consistent with numerous other decisions holding that the color of a capsule or tablet is not functional, see e.g., *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra* p. 13; *A.H. Robins Co.* v. *Medicine Chest Corp., supra* p. 12; *Marion Laboratories Inc.* v. *Michigan Pharmacal Corp.*, 338 F.Supp. 762 (E.D. Mich. 1972), aff'd without opinion, 473 F.2d 910 (6 Cir. 1973).

The decision in *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra,* is particularly pertinent since it involves another recent decision from a different circuit, the Third Circuit, on this question of look-alike prescription drug products. In *SK&F,* the plaintiff sold an oral diuretic in a maroon and white capsule under the trademark DYAZIDE. The defendant began selling a generic version of the drug, also in a maroon and white capsule. Plaintiff moved for a preliminary injunction, alleging violation of §43(a) of the Lanham Act and unfair competition under New Jersey law. In addition to color copying, the plaintiff in that case showed that four pharmacists had illegally substituted the generic look-alike capsules when filling prescriptions for DYAZIDE. The defendant, Premo, raised the same defenses as it raised in the instant case. The District Court granted a preliminary injunction, and was affirmed by the Court of Appeals. It held, in relevant part, that it was reasonable to conclude that Premo's use of a practically identical trade dress would facilitate passing off by pharmacists; that the trade dress had nothing

to do with the purpose or performance of the drug, or with its processing; that *Sears, Compco* did not bar relief; and that there was a violation of Section 43(a) of the Lanham Act and unfair competition under New Jersey law. As in the present case, the defendant there also urged that it could compete more effectively if allowed to continue copying the appearance of the innovator's product. The Court categorically rejected the argument (625 F.2d at p. 1067):

> "In light of these factors, Premo's implausible suggestion that the choice of a maroon and white gelatin capsule was made for functional reasons was not credited by the trial court. Even now it is not enjoined from marketing the combination drug covered by the expired SKF patent in a dosage form different from DYAZIDE. The only answer that Premo made when confronted with these factors was, in essence, that it could compete more effectively in the diuretic market if it could use the same maroon and white capsule color adopted by SKF for DYAZIDE. Probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound, or feel of equity."

Petitioners also urge that an injunction against the copying of the capsule colors conflicts with the decisions of this Court in *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964). Those cases held that a state could not prevent the copying of an article of merchandise which was, under the federal patent or copyright laws, in the public domain. Thus the drug product, cyclandelate, can be copied. Its trade dress, however, cannot. *Sears* and *Compco* specifically also held that a state could protect businesses in the use of their trademarks, labels, or trade dress. And, this Court has subsequently reconfirmed

the continued viability of the state law of unfair competition, *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470 (1974); *Goldstein* v. *California*, 412 U.S. 546 (1973); *Zachinni* v. *Scripps-Howard Broadcasting Co., supra*, p. 14. As aforesaid, the case does not involve any attempt to restrict the sale of the generic drug cyclandelate, once covered by patent. It involves the distinctive blue and blue/red capsules, or trade dress, in which that drug was sold by Ives.

In any event, the decision at issue finds a violation of federal, not state law, and the rationale of *Sears, Compco* is inapplicable for that reason also, *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra* p. 13 (625 F.2d at p. 1065). As Judge Friendly held on the first appeal (47a-48a):

> "The opinions can be read as limited to rights claimed under state unfair competition law granting protection equivalent to that of the federal patent or copyright laws for products not enjoying valid patent or copyright protection. The Court, it can be strongly argued, had no need to be concerned with marking out the boundaries of a federal tort over which it had complete control and which Congress could contract if the courts were pressing it further than that body desired."

For the same reason, namely that the decision rests on a federal statute, the arguments of one of the petitioners that it conflicts with New York State public policy is also not apposite.

It is also significant that the plaintiff had additional meritorious claims which the Court did not have to decide, having found liability under §32 of the Lanham Act. Given the Court's finding that the defendants had offered

no convincing evidence of functionality, and the undisputed facts that Ives had long and extensive use of blue and blue/red capsules and that they had been deliberately copied by the defendants, there were alternative grounds, under the reasoning of cases such as *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra* p. 13, for finding liability and enjoining use of the look-alike capsules under §43(a) of the Lanham Act or the law of unfair competition.

In summary, a fair reading of the Court of Appeals opinion shows that this is a classic case of passing off in which the manufacturer or distributor has furnished to the retailer the instrument of fraud enabling the subterfuge to occur without detection. It does not involve any restrictions on comparative advertising; it does not "significantly extend" the doctrine of contributory infringement; it is not a departure from existing trademark law; it does not result in the creation of a monopoly in the sale of the product cyclandelate; it does not have dire consesequences for future competition in the drug industry where other companies sell numerous generic drugs which do not duplicate the appearance of the innovator. Other courts have enjoined the simulation or copying of the appearance of a prescription drug capsule or tablet. The decision is completely consistent with this well established body of case law and with public policy, particularly insofar as it gives patients the ability, because of the color change, to detect illegal substitution and mislabelling and to better police the pricing practices of pharmacists dispensing the generic to assure that cost savings are passed on to the patient.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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Nos. 80-2182, 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

Certificate of Service

I hereby certify that on this day of July, 1981, three copies of the within Reply to Petitions for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit were served by hand on each of the following: Bass, Ullman & Lustigman, Attorneys for Petitioner Inwood Laboratories, Inc., 747 Third Avenue, New York, New York 10017; Kirschstein, Kirschstein, Ottinger & Cobrin, Attorneys for Petitioner Premo Pharmaceutical Laboratories, Inc., 666 Fifth Avenue, New York, New York 10103; and Salon, Marrow & Dyckman, Attorneys for Petitioners Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Co., Inc., 41 East 42nd Street, New York, New York 10017. I further certify that all parties required to be served have been served.

/s/ MARIE V. DRISCOLL

MARIE V. DRISCOLL

No. 80-2182

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In The

Supreme Court of the United States

October Term, 1980

INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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§43(a) 2, 3

No. 80-2182

In The

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October Term, 1981

INWOOD LABORATORIES, INC., and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioners Inwood Laboratories, Inc. and Premo Pharmaceutical Laboratories, Inc. respectfully submit this reply brief in support of their petition for a writ of *certiorari* to the United States Court of Appeals for the Second Circuit.

ARGUMENT

Respondent ignores the critical issue presented in the petition for certiorari: did trademark infringement occur?

Respondent Ives Laboratories, Inc. ("Ives") has deliberately chosen not to deal with the questions presented by petitioners and the holding of the United States Court of Appeals for the Second Circuit. The Court of Appeals held that pharmacists committed trademark infringement within the meaning of §32 of the Lanham Act (15 U.S.C. §1114) when, either orally or by labeling a prescription vial, they advised a patient that the dispensed generic cyclandelate product, which was prescribed by a physician and was similar in appearance to Ives' Cyclospasmol product, was "Generic Cyclospasmol." The Court further determined that petitioners, by manufacturing an equivalent drug in the same color as Ives' product, were guilty of "contributory trademark infringement" and therefore should be enjoined from copying a functional feature of a product which had no secondary meaning. *See generally, Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 638 F. 2d 538 (2d Cir. 1981) (71a).

Instead of addressing this issue, Ives erects a strawman. It blithely states that the Second Circuit's theory of liability is not crucial in this case because Ives contends petitioners also violated §43(a) of the Lanham Act, and/or various aspects of the state law of unfair competition by manufacturing prescription drug products with the same capsule colors as Ives' product. In support of its argument, Ives cites various cases involving the colorations of prescription drug products which were decided under theories other than contributory trademark infringement and involved instances of impermissible substitution of the generic product for the brand-name product. *See* Respondent's Reply to Petition for *Certiorari*, at 12-13 ("Respondent's Reply").

In each of those cases, however, in sharp contrast to the instant one, the plaintiff brand-name manufacturer, in order to secure an injunction against color copying, had to show *secondary meaning*, and that the color was *non-functional* in order to hold the generic company liable. These concepts — secondary meaning and functionality — are at the heart of §43(a) of the Lanham Act. *See e.g., Vibrant Sales, Inc. v. The New Body Boutique, Inc.*, ____ F. 2d ____, No. 80-7877 (2d Cir. June 29, 1981).[1] Additionally, the case at bar is clearly distinguishable in light of the Second Circuit's express finding that the instances of impermissible substitution of petitioners' generic product for Ives' was *de minimis* and did not warrant a finding of contributory trademark infringement. *See Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 601 F. 2d 631, 644 (2d Cir. 1981) (52a-53a).

As extensively discussed in the petition for *certiorari*, the holding of the Second Circuit in the instant case automatically guarantees rights in the color of a drug product *without* any showing of secondary meaning or functionality. This result was reached by application of the erroneous theory that pharmacists' truthful comparative use of Ives' trademark ("Generic Cyclospasmol") constituted trademark infringement under §32 of the Lanham Act. This is the critical premise of the Second Circuit's decision. This is the critical issue raised by the petition for *certiorari*. This is the critical error in the opinion below. Yet this is the question which Ives chose not to even address.

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1. As the Second Circuit recently noted:

> "An action . . . which is predicated almost entirely on the false designation of origin leg of 43(a), *can only succeed if the features allegedly copied have acquired secondary meaning in the marketplace and are non-functional.*" *Id.* at 4060 (emphasis added).

It should also be pointed out that Ives' attempts to treat petitioners' practice of marketing generic drugs in an appearance similar to their brand-name counterparts as an isolated exception to the general methods of marketing utilized by the prescription drug industry. Nothing could be further from the truth. As the *amicus* briefs submitted by the National Association of Pharmaceutical Manufacturers, the American Association of Retired Persons, and the National Retired Teachers Association amply demonstrate, the practice of marketing generic drugs in the same color as their brand-name counterparts is traditional, widespread and critical to the patients of this nation — especially the elderly.

More significantly, Ives' attempt to portray petitioners' marketing practices as unusual or atypical conveniently overlooks the fact that on March 30, 1981, Ives commenced an action against *sixteen* other generic manufacturers and distributors of cyclandelate on the ground that they too sell generic cyclandelate products in the same colors as Ives' Cyclospasmol and thereby are violating, *inter alia*, §32 of the Lanham Act. *See Ives Laboratories, Inc. v. Bioline Laboratories, Inc., et al.*, Civil Action No. 81-914 (VPB) (D.N.J., Complaint filed Mar. 30, 1981).[2]

It is respectfully submitted that the decision of the Second Circuit in the instant case is legally incorrect and will have drastic and harmful consequences for generic drug companies in their effort to provide the public with low cost, therapeutically equivalent alternatives to brand-name drugs.

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2. As previously noted, Ives refers to a recent series of cases in the Third and Eighth Circuits wherein large pharmaceutical manufacturers sued generic drug companies (other than petitioners herein) for copying the appearance of a prescription drug product. *See* Respondent's Reply at 12-13. Although, these cases were determined under significantly different theories of law, they demonstrate the extensive and historical practice of marketing generic equivalents in the same color as their brand-name counterparts.

CONCLUSION

For the reasons stated herein and for the reasons stated in the petition, it is respectfully requested that a writ of *certiorari* issue to review the judgment of the United States Court of Appeals.

Respectfully submitted,

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CLERK

No. 80-2182

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

RESPONDENT'S OPPOSITION TO MOTIONS FOR LEAVE TO FILE BRIEFS AMICUS CURIAE

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No. 80-2182

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Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

RESPONDENT'S OPPOSITION TO MOTIONS FOR LEAVE TO FILE BRIEFS AMICUS CURIAE IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

Two motions have been filed for leave to file briefs amicus curiae in support of the Petition for Writ of Certiorari filed in this case by Inwood Laboratories, Inc. and Premo Pharmaceutical Laboratories, Inc. One was filed by the National Association of Pharmaceutical Manufacturers, Inc. and the other by two organizations, The American Association of Retired Persons and The National Retired Teachers Association. Both Motions were served on the attorneys representing Respondent after Respondent had served and filed its Brief in Opposition to the Petitions for Writ of Certiorari.

Respondent hereby opposes these Motions and asks that the Court deny the organizations leave to file briefs amicus curiae for the following reasons.

The interests of the moving parties are adequately represented in the two Petitions for Certiorari already filed in this case. A review of the motions shows that the arguments that these organizations propose to make are merely cumulative to those made by the Petitioners Inwood and Premo and by the other defendants in the case who are Petitioners in the corresponding Petition identified under Docket No. 81-11. Although the moving parties do not mention, and thus are apparently not attempting to support, this other Petition for Certiorari they made many of the same arguments as appear in that Petition. It should be noted also that the positions espoused by The National Association of Pharmaceutical Manufacturers, Inc. is particularly a repeat of the Inwood and Premo position, undoubtedly because the same law firm prepared the Brief for Petitioner Inwood and the Motion and Brief for said Association.

It is also apparent that a principal argument that the moving parties intend to raise is not appropriately before this Court. They urge that there is an alleged conflict of the Court's decision with the public policy of various states which have passed generic drug substitution laws. The decision, however, was one interpreting a federal statute and state policy can be of no relevance to a Court's interpretation of such a statute.

Finally, the moving parties refer repeatedly to competitive conditions in the drug industry, the history of competition in that industry, and the cost of drugs. The action before this Court, and before the Court of Appeals for the Second Circuit, involves a drug sold in capsules which

simulate the appearance of the Respondent's capsules, and which were illegally substituted for and wrongfully passed off as Respondent's product. The case rests on particular facts and does not address, nor does the record contain evidence of, general competitive conditions in the drug industry, except insofar as it was shown that other generic drugs are marketed in trade dress that does not copy the innovator. The positions which the organizations wish to take before this Court should not be raised in this litigation, but are more appropriately of the type to be addressed to the legislature.

CONCLUSION

For the foregoing reasons, Respondent respectfully requests that the Motions for Leave to File Briefs Amicus Curiae be in all respects denied.

Respectfully submitted,

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No. 80-2182

In the

Supreme Court of the United States

October Term, 1981

Darby Drug Co., Inc., Inwood Laboratories Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.,

Petitioners,

—against—

Ives Laboratories, Inc.,

Respondent.

Certificate of Service

I hereby certify that on this day of , 1981, three copies of the within Respondent's Opposition to Motions for Leave to File Briefs Amicus Curiae were served by mail on each of the following: Bass, Ulman & Lustigman, Attorneys for Petitioner Inwood Laboratories, Inc., 747 Third Avenue, New York, New York 10017; Kirschstein, Kirschstein, Ottinger & Cobrin, Attorneys for Petitioner Premo Pharmaceutical Laboratories, Inc., 666 Fifth Avenue, New York, New York 10103; Salon, Marrow & Dyckman, Attorneys for Petitioners Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Co., Inc., 41 East 42nd Street, New York, New York 10017; Miller, Singer, Michaelson & Raives, Attorneys for The American Association of Retired Persons and The National Retired Teachers

Association, 555 Madison Avenue, New York, New York 10022; and Milton A. Bass, Attorney for National Association of Pharmaceutical Manufacturers, Inc., 747 Third Avenue, New York, New York 10017. I further certify that all parties required to be served have been served.

/s/ MARIE V. DRISCOLL

MARIE V. DRISCOLL

MOTION FILED

JUL 27 1981

IN THE

Supreme Court of the United States

October Term, 1980

No. 80-2182

INWOOD LABORATORIES, INC. and
PREMO PHARMACEUTICAL LABORATORIES, INC.,
Petitioners,

against

IVES LABORATORIES, INC.
Respondent.

ON A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE AND BRIEF AMICI CURIAE OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS AND THE NATIONAL RETIRED TEACHERS ASSOCIATION IN SUPPORT OF THE PETITIONER

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- against -

IVES LABORATORIES, INC.,
Respondent.

ON A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE* IN SUPPORT OF THE PETITIONER AND STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Association of Retired Persons (AARP) and the National Retired Teachers Association (NRTA), of 1909 K Street, N.W., Washington, D. C. 20049, respectively move the Court pursuant to Rule 36 of the Rules of the United States Supreme Court for permission to file the attached brief *amici curiae* on a Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit. The grounds for this motion, which grounds also disclose the interest of the *amici,* are set forth below.

AARP and NRTA are affiliated and jointly administered not-for-profit membership corporations of more than 12,500,000 persons over the age of 55. This figure represents approximately one out of four people over the age of

55 nationwide, the largest organized group of older Americans in the country. Among the purposes of AARP are: to enhance the quality of life for older persons; to promote independence, dignity and purpose for older persons; to lead in determining the role and place of older persons in society; and to improve the image of aging. Among the purposes of NRTA are: to promote the social welfare and needs of retired teachers, administrators, and all other persons eligible for membership, to improve the quality of life for retired teachers, school administrators, and all older Americans, to the end that aging is achieved with independence, dignity and purpose; and to sponsor research on physical, psychological, social, economic, and other aspects of aging.

Inwood Laboratories, Inc. and Premo Pharmaceutical Laboratories, Inc.,[1] manufacturers of the generic drug cyclandelate, filed their Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit seeking reversal of the holding that the generic manufacturers were liable for contributory trademark infringement by virtue of their packaging of cyclandelate in the same color capsule as used by respondent, in conjunction with their employment of truthful comparative advertising. The questions presented by the Petition are: (1) whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement; and (2) whether Section 32 of the Lanham Act, 15 U.S.C. §1114, grants a trademark owner monopoly rights in the color of its product.

The opinion of the Court below answering both questions in the affirmative seriously impinges upon the interests of the elderly.

The generic drug industry provides vital service to the elderly: it offers generic equivalents such as cyclandelate as alternatives to the higher priced brand-name drugs. It

1. Hereinafter referred to as the "generic manufacturers."

promotes competition in the pharmaceutical marketplace, with the resultant effect of cost containment. The decision of the Second Circuit places into serious question the future competitive capacity of the generic drug industry.

The color in which drugs are packaged involves far more than aesthetics; it is a vital competitive characteristic. During the period in which their patent is in effect, brand-name companies establish a color which identifies a particular drug in the eyes of dispensers, *i.e.* physicians, hospitals, and pharmacists, as well as in those of the patient. The introduction of a generic equivalent dressed in a different color will be met with substantial resistance, by reason of which the generic competitor will be foreclosed from a substantial pocket of the market.

Thus, the result of the Second Circuit's decision, severely restricting the ability of generic manufacturers to dress their drugs in the "accepted" colors used by the brand-name producers, will stifle competition and prices will inevitably rise. This threat to the continued availability of lower-priced, bioequivalent generic drugs, and the downward pressure on prices created by their competition with brand-name drugs, seriously prejudice older persons, a category of Americans with expanded need for the drugs, but with often limited means to pay for them.

As retired persons, many members of AARP and NRTA live on relatively fixed incomes and, because of their advanced age, many also depend on regular or frequent administration of pharmaceuticals for their continued well being. Because of the need to contain the already high, and rapidly increasing, cost of health care, including expenses for drugs, this case is especially critical to the health and welfare of AARP and NRTA members and of all older Americans.

The elderly spend a far greater amount *per capita* on health care each year than younger persons. In 1979, the average annual health care expenditure for persons over 65

was $2,257 or 3½ times the average amount expended by persons under 65. While older Americans comprise only 11.2% of the population, they spend 29% of the total nationwide expenditure for personal health care.[2] With respect to drug costs, all Americans expended $15,098,000,000 for drugs and drug sundries in the calendar year 1978.[3] Of this figure, $3,331,000,000 or 22% of the nationwide total was spent by persons 65 years of age and older.[4] On a *per capita* basis, older persons' drug costs are nearly twice as much as those of younger persons.[5]

Older Americans pay for the overwhelming majority of these costs out of their own pocket. Medicare provides no reimbursement for prescription drugs. Medicaid is only available for the poor, and indeed only provides benefits for approximately 50% of the poor. Consequently, only 15.6% of drug costs to the elderly are covered by the combination of Medicare and Medicaid and other types of public assistance.[6] Thus the elderly must privately finance a full 84.4% of these drug costs, largely out of their fixed, and increasingly inadequate, incomes.

Since the over 12.5 million members of the amici are directly and severely affected by the cost of drugs, and because the decision of the Second Circuit endangers the continued viability of the generic drug alternative, amici have a vital interest in the ultimate question presented: whether Section 32 of the Lanham Act grants a trademark owner a monopoly over the color of its product.

The amici have been unable to obtain the consent of the respondent to the filing of the attached brief, thus necessitating this motion.

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2. Gibson, *National Health Expenditures*, 1979, 2 HEALTH CARE FINANCING REVIEW 1 (Summer 1980); Fisher, *Differences by Age Groups In Health Care Spending*, 1 HEALTH CARE FINANCING REVIEW 4 (Spring 1980).

3. Fisher, *Differences By Age Groups in Health Care Spending*, 1 HEALTH CARE FINANCING REVIEW, 4 at 81 (Spring, 1980).

4. *Id.*

5. *Id.*

6. *Id.* at *89.*

WHEREFORE, AARP and NRTA respectfully move for permission to file the attached brief amici curiae in support of the Petition for a Writ of Certiorari in this matter.

Respectfully submitted,

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IN THE

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- against -

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Respondent.

BRIEF AMICI CURIAE IN SUPPORT OF THE PETITIONER

INTRODUCTION

The overriding interest of AARP and NRTA in the health care field is to foster and promote efficient delivery to the elderly of the best possible services at the least possible cost, thus making them readily available even to persons living within fixed and limited incomes. Amici steadfastly maintain that elimination of all anti-competitive barriers in the drug industry is essential to the achievement of this ultimate goal.

Brand name manufacturers develop an overwhelming head-start in the market for a particular drug, Cyclospasmo being a prime example. By virtue of their patent, they enjoy a seventeen year product monopoly, and direct an exhaustive advertising campaign towards physicians. As a consequence, most physicians identify the drug with its brand name and write prescriptions accordingly.

In recognition of the vast competitive superiority thus obtained by brand-name manufacturers, the legislatures of 48 states have adopted so-called "generic drug substitution" statutes which either require or allow the dispensing pharmacist to substitute a generic drug, unless the physician otherwise directs. These statutes are evidence of the pervasive local interest in fostering effective competition in the pharmaceutical market in order to achieve some measure of cost containment.

Instead of accommodating this social interest, the Second Circuit has ignored it, and indeed done it considerable violence, by effectively granting brand-name producers a monopoly over the color in which their drug is produced. These colors perform several functions with regard to health, drug identification and patient compliance such that denial of their use to generic manufacturers, who come into the marketplace long after the brand-name drug has secured a strong foot-hold, puts them at a severe competitive disadvantage. And any threat to the economic viability of the generic drug industry, carries with it a concommitant threat to the cost containment achieved by their competitive presence. The consequence of the Second Circuit's decision will be to provide brand-name drug manufacturers with an untoward competitive advantage, largely at the expense of older Americans.

ARGUMENT

Amici respectfully join in the legal argument advanced by the Petitioners. We respectfully highlight below several points of direct concern to AARP and NRTA.

POINT I

THE SECOND CIRCUIT'S DECISION GRANTS BRAND-NAME DRUG MANUFACTURERS A DECIDED MARKETING ADVANTAGE BY VIRTUE OF THE FUNCTIONALITY OF DRUG COLOR AND THUS THREATENS THE CONTINUED COMPETITIVE CAPACITY OF GENERIC DRUG MANUFACTURERS

The colors used in drug packaging are functional in various ways, particularly as regards the elderly. As expressly found by the District Court,[1] many patients, especially elderly patients, associate the color of a drug with its therapeutic effect. Since the brand-name product, in the color of the capsule containing it, is the exclusive source of a drug while it is under patent, a drug will be identified as "my little blue heart pill." When a bioequivalent generic drug becomes available, but in a different color, there is considerable distrust with respect to the generic alternative. This distrust may lead to lack of patient compliance in a state, such as New York, which has adopted a mandatory generic drug substitution statute. When faced with patient resistance to drugs packaged in an unfamilar color, physicians will prescribe the brand-name drug to insure that reluctant patients will take it. Indeed, problems with patient compliance may convince physicians to insist as a matter of policy that pharmacists fill prescriptions with brand-name drugs, thereby denying all his patients access to lower-priced generics.

Second, even if patients eventually accept variations in color, they do so only after considerable anxiety and confusion. This can often result in the patient being deprived of the so-called "placebo effect" experienced by many patients, *i.e.* the psychological healing power caused by the confidence and assurance of a patient taking medication that he has been advised would help him.

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1. *See* Appendix C to the Petition, p. 63a

Third, many elderly patients who take multiple medications identify each drug by its color. Color variations in the same medicine would upset the identification procedures employed by elderly patients, and create widespread confusion.

Fourth, the potential for confusion has lead hospitals, pharmacies and wholesalers to refuse to purchase generic drugs colored differently than the brand-name drugs.

Fifth, uniform drug coloring can save lives, as it can serve to identify drug overdoses for physicians and emergency personnel acting in life-threatening situations.

In light of the functionality of drug color, the District Court found, as a matter of fact, that "to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage."[2] The District Court further found that "color is an important ingredient in the commercial success of the product."[3]

Labeling these functionality aspects to the issue "unconvincing,"[4] the Second Circuit held that the generic manufacturers' imitation of the color in which respondent packaged its Cyclospasmol constituted "contributory trademark infringement" violative of Section 32 of the Lanham Act. The Court of Appeals reasoned that the generic manufacturers should have reasonably anticipated that some druggists might intentionally or accidentally apply respondent's trademark to cyclandelate.[5] Because this possibility will always exist, the Court of Appeals has effectively granted a monopoly over color to brand-name drug manufacturers, and given them a decided advantage over generic competitors who must sell the generic drug in a far less marketable color. Consequently, the Second Circuit, in a

2. *Id.* at 63a.
3. *Id.*
4. *See* Appendix D to the Petition, p. 85a.
5. *See Id.* at 82 a-83a.

radical departure from settled law,[6] has granted proprietary rights in color in the absence of "secondary meaning" and despite evidence of functionality, and has sharply contradicted the federal policy, as enunciated by this Court, favoring the exact copying of unpatented merchandise.[7] In so doing, it seems to have foresaken the interest of the public in general, and that of the elderly in particular, in favor of the profit interest of the drug manufacturers.

To the extent that generic manufacturers cannot compete with the brand-name producers in light of the color monopoly granted by the Court of Appeals in this case, and thus are forced out of the market, the brand-name manufacturers will then enjoy restoration of their product monopoly which had expired along with their patent. This would remove any hope for cost containment in the pharmaceutical industry.

To the extent that generic manufacturers manage to remain in the market, drug identification by color will no longer be possible, because of the inevitable claim of trademark infringement. Furthermore, patients or physicians whose confidence depends upon the functionality of drug color must suffer the higher price commanded by the brand-name companies. These functional aspects principally affect the elderly, and thus will be mainly paid for by a group of Americans least able to afford it.

CONCLUSION

Amici have a special interest and concern in expanding the competitive forces at work in the pharmaceutical market. Granting brand-name producers a monopoly over product color in light of its functional nature, will seriously limit or eliminate these competitive forces, will preclude

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6. *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Upjohn Co. V Schwartz*, 246 F.2d 254 (2d Cir. 1957).

7. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964); *Compro Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 238 (1964).

drug identification through uniform coloring, and will reserve the functional benefits of drug color to those willing and able to pay higher prices for it.

WHEREFORE, amici respectfully request that the Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit be granted.

Respectfully submitted,

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Dated: July , 1981
New York, New York

No. 80-2182

MOTION FILED

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INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

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Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

and

BRIEF OF AMICUS CURIAE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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No. 80-2182

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Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The National Association of Pharmaceutical Manufacturers, Inc., ("NAPM") by its undersigned General Counsel, respectfully moves, pursuant to Rules 36 and 42.2(b) of the Rules of this Court, for an order granting it leave to file an *amicus curiae* brief in support of the petition for a writ of certiorari filed in the above-entitled matter. The proposed brief is annexed hereto.

INTEREST OF THE AMICUS CURIAE

NAPM is a national trade association representing more than 100 manufacturers and distributors of prescription and "over-the-counter" pharmaceutical products throughout the United States. For many years, NAPM has been the leading spokesman for what is commonly known as the generic drug industry. NAPM has represented the industry in the courts (both as party and as an *amicus*), before administrative tribunals, as well as in the legislative arena by participating in hearings before Congress and the legislatures of numerous states. The petitioners herein, Inwood Laboratories, Inc. ("Inwood") and Premo Pharmaceutical Laboratories, Inc. ("Premo"), are members of NAPM.*

NAPM has reviewed the petition for a writ of certiorari filed by its members Inwood and Premo and concurs therein. However, upon such review, NAPM believes that certain additional important matters should be called to the Court's attention and for that purpose seeks to file its proposed *amicus curiae* brief.

The proposed brief succinctly discusses the following critical points in urging that this Court grant the petition for a writ of certiorari:

1. The historical nature of competition in the pharmaceutical field; and

2. The profound nationwide consequences which the decision of the United States Court of Appeals for the Second Circuit will cause unless review is granted.

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* The law firm of NAPM's General Counsel also represents Inwood, one of the petitioners herein.

As the representatives of the generic pharmaceutical industry, we respectfully believe that NAPM should be heard with regard to a petition for a writ of certiorari which vitally affects the interest of its members. Accordingly, pursuant to Rule 36.1 of this Court, the office of the undersigned communicated with counsel for the respondent to seek its consent to the filing of NAPM's *amicus* brief. Counsel for respondent declined to grant such consent and further declined to give any reasons for such refusal. Petitioners Inwood and Premo have consented to the filing of an *amicus* brief by their trade association.

It is respectfully requested that in deciding whether to grant certiorari in a matter vitally affecting the generic pharmaceutical industry, the Court should have the benefit of the additional views of that industry's trade association.

NAPM, by its General Counsel, a member of the Bar of this Court, therefore respectfully requests that NAPM's motion for leave to file the annexed *amicus* brief be granted.

Dated: New York, New York
July 23, 1981

Respectfully submitted,

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General Counsel
National Association of
Phamaceutical Manufacturers, Inc.

No. 80-2182

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BRIEF OF AMICUS CURIAE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

QUESTIONS PRESENTED

NAPM concurs in the questions presented in the petition for a writ of certiorari. For convenience, those questions are set forth below:

1. Whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement?

2. Whether Section 32 of the Lanham Act (15 U.S.C. §1114) grants a trademark owner monopoly rights in the color of its product?

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Grussing, Purohit, Stewart, "Drug Product Selection in Illinois: An Evaluation of PA 80-976 After One Year of Experience" (May 30, 1980) 2

The American Druggist, "The Top 200 Prescription Drugs of 1980", Vol. 183 at 49 (Feb. 1981) 2

INTEREST OF THE AMICUS CURIAE

The interest of *amicus curiae* NAPM is set forth in its motion for leave to file the instant *amicus curiae* brief. *See* p. 2, *infra*. Accordingly, it will not be repeated herein.

REASONS FOR GRANTING THE WRIT

The decision of the Second Circuit threatens the traditional pattern of competition in the pharmaceutical industry.

NAPM wishes to emphasize to this Court that the labeling, advertising and color issues set forth by the petitioners do not stem from isolated marketing practices limited to the companies presently before the Court. Pharmaceutical products are known in the scientific community by their long and complicated chemical names. Historically, generic competition with large brand-name pharmaceuticals has been possible because the generic product could be identified only by designating it as a therapeutic equivalent for the more widely known brand-name pharmaceutical. Similarly, we respectfully advise the Court that the practice of marketing generic prescription products in the same color as that of brand-name products is firmly established, going back more than 50 years.

These twin aspects of the marketing of generic products, *i.e.*, identification of generic equivalents and marketing in similar color configurations, were an accepted part of the pharmaceutical trade and evoked no significant opposition from the brand-name drug companies until the last few years. Suddenly, these brand-name companies initiated a virtual avalanche of litigation against generic drug companies seeking to reverse the historical pattern, attacking both the use of similar colors and the manner of identification of generic equivalents. The decision of the United States Court of Appeals for the Second Circuit, in *Ives Laboratories, Inc. v. Darby Drug Co.*,

Inc., 638 F. 2d 538 (2d Cir. 1981) (hereinafter "*Ives*"), prohibits these long-standing competitive practices in the drug industry by invoking the novel theory of contributory trademark infringement.

The Court may wonder what accounts for this recent assault by brand-name companies upon these traditional modes of competition. The answer lies in the fact that it is only in recent years that generic drug competition has become a significant force in the marketplace.

During the past decade, forty-nine states, Puerto Rico and the District of Columbia, have adopted legislation which provides for substitution of less-expensive generic products for their brand-name counterparts when authorized by a physician. A detailed study of the effect of drug substitution laws recently conducted by the University of Illinois concluded that:

> "Data from the Illinois study *strongly supported the contention that significant cost savings accrued to consumers* when [drug substitution] occurred." *See* Grussing, Purohit, Stewart, "Drug Product Selection in Illinois: An Evaluation of PA 80-976 After One Year of Experience," Summary of Major Findings at 2 (May 30, 1980).

Moreover, the Illinois study of six other states[1] revealed that significant cost savings resulted in each state when generic drug substitution occurred. *Id.* at 87. The savings ranged from a low of $.86 to a high of $1.92 for *each* prescription. In 1980, more than 126 million prescriptions were filled in the United States. In December, 1980, the average retail price of a prescription was $9.20. *See The American Druggist*, "The Top 200 Prescription Drugs of 1980," Vol. 183 at 49, 52 (Feb. 1981). Thus, it can be

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1. Michigan, Wisconsin, Florida, Vermont, Rhode Island and Delaware.

readily agreed that the use of generic drugs affords the consumers of the nation potential savings of tens of millions of dollars.[2]

These substantial savings are jeopardized by the ill-founded decision of the Second Circuit in the *Ives* case. As Judge Nickerson noted in *Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 488 F. Supp. 394 (E.D.N.Y. 1980) (54a):

> "[T]he policy expressed in the New York Education Law [is] to encourage legal substitution of lower-priced drugs. . . . *To require different capsule colors . . . would also severely inhibit legal substitution which the legislature deems to be in the public interest." Id.* at 401 (69a).[3] (Emphasis added.)

The public interest in reducing the high cost of drugs was the impetus for the nearly unanimous adoption of drug substitution laws in the United States. Justice Blackmun eloquently articulated this interest in *Virginia State Board of Pharmacy v. Virginia Consumer Council*, 425 U.S. 748 (1976):

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2. For example, on April 10, 1981, the Department of Health for the State of New Jersey announced that its two-year old generic drug law saved consumers over $6 million. Similarly, on March 3, 1981, the New Hampshire Council on Aging stated that New Hampshire's then-proposed drug substitution law could save the elderly $2 million a year. One month prior, on February 3, 1981, a statewide community organization announced that if Texas adopted a drug substitution law, consumers would save upwards of $30 million. Texas became the 49th state to adopt such a law on May 28, 1981. Ten days later, on June 8, 1981, the New York City Department of Consumer Affairs announced that consumers had paid $12 million unnecessarily for medications because doctors and pharmacists have disregarded the state's generic drug law.

3. All "a" references are to the appendix annexed to the petition for certiorari.

> "Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. *A disproportionate amount of their income tends to be spent on prescription drugs;* yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent. Where drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 763-764. (Emphasis added.) *See also, id.* at 763, n.18.

What has happened is, therefore, obvious. Facing a growing public policy trend favoring lower-cost generic pharmaceutical products, the brand-name companies have reacted by seeking to undercut the traditional ability of the generic industry to compete effectively. The Second Circuit decision fosters this result by holding that identification of a drug product as a generic equivalent constitutes "trademark infringement", and engaging in a strained analysis to hold generic manufacturers liable as contributory trademark infringers. The result is a grant of monopoly color rights to brand-name companies and a *de facto* extension of their drug patents.

The far-reaching and potentially disastrous consequences of the Second Circuit decision derive from the fact that, in the first instance, it strikes at the very heart of the entire concept of generic competition.

The majority opinion failed to recognize that comparative advertising which cross-references a generic product to a brand-name product, is a long-established and essential custom of the trade. Such advertising is necessary since most purchasers,

including physicians, are only familiar with the brand-name product because of the enormous amount of money such companies spend in promotion to doctors and pharmacists. Indeed, physician unfamiliarity with generic names is evidenced by the structure of the New York generic substitution law, which permits the physician to list the brand-name product as the medication prescribed, but to sign his name on the prescription form above the heading "substitution permissible." In such an instance, a generic drug can be substituted for the brand-name product listed by the physician. Without cross-referencing generic products to brand-name products, widespread confusion would result.

If the trademark laws can be construed to prohibit the description of a drug product as a generic version of a brand-name product, the effective means of communication between the generic drug manufacturer, his customers, pharmacists and the ultimate consuming public, is virtually cut off. The unfamiliar technical chemical names offer no recourse. How many persons (even professional ones) know, for example, that such trademarked drugs as Darvon and Librium are identified respectively as Propoxyphene Hydrochloride and Chlordiazepoxide Hydrochloride?

To prohibit, as the Second Circuit does, identification of generic equivalents with brand-name products would cause chaos in the effort to market generic drugs.[4] As the dissenting opinion of Judge Mulligan points out, ". . . juxtaposition of the

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4. The Second Circuit holding of contributory trademark infringement was based on certain critical "additional evidence" adduced by respondent. *Ives*, 638 F. 2d at 542 (80a). Those instances all related to pharmacists who truthfully labeled or described the product as "Generic Cyclospasmol". No passing off or illegal substitution was involved. *Ives* holds that such labeling or description constitutes trademark infringement for which NAPM's members were held liable as "contributory infringers".

generic and brand-name drug would be imperative for generic manufacturers to compete effectively [citation omitted]." *Ives*, 638 F. 2d at 547, n. 4 (90a).

A more subtle, but no less significant consequence, flows from the monopoly rights granted to the brand-name companies in the color of their pharmaceutical products by virtue of the Second Circuit's decision. Obviously, these companies hope that a difference in color will induce consumers to resist generic drug products made available to them under the generic substitution laws. In view of Judge Nickerson's compelling factual findings as to the functionality of color, the Second Circuit's grant of a color monopoly (under the supposed rubric of contributory trademark infringement), virtually guarantees that the brand-name goal of consumer resistance to generic drugs will be realized.

The psychological reaction which all patients have to drugs which are designed to regulate critical body functions such as heart rate cannot be overstated, especially if the patient has been taking the same colored capsule or tablet for many years with positive therapeutic effects. Current medical theory recognizes that this type of psychological efficacy association produces an actual sympathetic therapeutic response to the condition being treated. *See e.g., United States v. An Article . . . Acu-Dot*, 483 F. Supp. 1311, 1314, n. 3 (N.D. Ohio 1980); *F.T.C. v. Simeon Management Corp.*, 391 F. Supp. 697, 705 (N.D. Cal. 1975), *aff'd*, 532 F. 2d 708 (9th Cir. 1976). It cannot be disputed that changes in color will interfere with the psychological efficacy association.

Moreover, generic substitution laws, which are designed to further the purposes which this Court protected in *Virginia Pharmacy*, will be severely undercut if the Second Circuit decision is left to stand. Simply put, the elderly, for whom the

particular drug at issue is primarily prescribed, will not purchase or will resist purchasing a generic drug which is different in color from the brand-name product which they have previously purchased for many years, even though the different colored generic would be less expensive. Indeed, the record shows dramatic evidence of a hospital's refusal to purchase the generic product at issue because it was not in the same color configuration as the brand-name counterpart marketed by respondent. *See Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 488 F. Supp. at 399 (64a).

NAPM's members and the generic drug industry seek nothing more than the opportunity to engage in vigorous *fair competition* with brand-name companies — competition which in recent years the brand-name companies have made every attempt to suppress.[5] *See, e.g.*, "Competition in the Drug Industry: Hearing Before the Subcommittee on Oversight and

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5. The petition for certiorari deals with the legal question of whether the actions of the pharmacist in truthfully labeling a product "Generic Cyclospasmol" constitute trademark infringement. NAPM respectfully wishes to add that the Second Circuit opinion, which seems to paint pharmacists as willing criminal cheaters of the public, stands in stark contrast to this Court's description of the "high degree of professionalism on the part of licensed pharmacists." *Virginia Pharmacy*, 425 U.S. at 766. The Court observed:

> "[That professionalism] is exercised in a number of ways for the *consumers benefit* . . . . *The expertise of the pharmacist* may supplement that of a prescribing physician. . . . The pharmacists, *a specialist in the potencies and dangers of drugs*, may even be consulted by the physician as to what to prescribe . . . .Some pharmacists . . .'monitor' the health problems and drug consumption of customers who come to them repeatedly. A pharmacist who has a continuous relationship with his customer *is in the best position, of course, to exert professional skills for the customer's protection.*" *Id.* at 766-767. (Emphasis added.)

Investigations of the House Committee on Energy and Commerce" (91 Cong., 1st Sess., March 10, 1981). *See also, Hoffman La-Roche, Inc. v. Harris*, 484 F. Supp. 58, 65 (D. D.C. 1979). The decision of the Second Circuit destroys that ability to effectively compete for the patient's dollar, and with the loss of that right comes the loss of savings in untold millions to consumers and a subversion of the generic substitution laws of this nation.

CONCLUSION

It is respectfully requested that for the reasons set forth herein a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit.

Respectfully submitted,

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In The

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF ON THE MERITS FOR PETITIONER INWOOD LABORATORIES, INC.

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QUESTIONS PRESENTED

I. Whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement.

II. Whether Section 32 of the Lanham Act [15 U.S.C. §1114] grants a trademark owner monopoly rights in the color of its product.

PARTIES TO THE PROCEEDING BELOW

The parties to the proceeding whose judgment is sought to be reviewed, in addition to Inwood Laboratories, Inc. ("Inwood"), are: Premo Pharmaceutical Laboratories, Inc. ("Premo"); Darby Drug Co., Inc. ("Darby"); MD Pharmaceutical Company, Inc. ("MD"); Rugby Laboratories, Inc. ("Rugby"); and Sherry Pharmaceutical Co., Inc. ("Sherry"). Those petitioners are filing separate briefs with this Court. Supreme Court Rule 34.1(b). Additionally, as required by Supreme Court Rule 28.1, Inwood listed its corporate affiliations in its petition for *certiorari*. Said listing is currently accurate.

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No. 80-2182
No. 81-11

In The

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF ON THE MERITS FOR PETITIONER INWOOD LABORATORIES, INC.

OPINIONS BELOW

For convenience, the five opinions rendered below were reprinted in the Appendices to the Petition for *Certiorari* ("Pet.App.") in chronological order.

The first opinion of the District Court, denying respondent's request for preliminary injunctive relief on its primary claims, is officially reported at 455 F.Supp. 939 (E.D.N.Y. 1978), and reprinted in Pet.App. A at 1a-27a (hereinafter referred to as "*Ives* I"). The Court of Appeals' decision, affirming the District Court's denial of preliminary injunctive relief, is officially reported at 601 F.2d 631 (2d Cir. 1979), and reprinted in Pet.App. B at 28a-53a (hereinafter "*Ives* II").

The second opinion of the District Court, dismissing respondent's complaint, is officially reported at 488 F.Supp. 394 (E.D.N.Y. 1980), and reprinted in Pet.App. C at 54a-70a (hereinafter "*Ives* III"). The opinion of the Court of Appeals at issue herein, reversing the District Court, is officially reported at 638 F.2d 538 (2d Cir. 1981), and reprinted in Pet.App. D at 71a-93a (hereinafter "*Ives* IV"). A subsequent order by the Court of Appeals denied petitioners' timely petition for rehearing or rehearing *en banc* without opinion on February 25, 1981. The order is not officially reported, and a copy of this order is reprinted in Pet.App. E at 94a-95a. Acting on the mandate of the Court of Appeals, on May 12, 1981, the District Court entered an order which, *inter alia*, enjoined petitioners from marketing a drug product in the same capsule colors as those sold by respondent. The memorandum and order are not yet officially reported, and copies thereof are reprinted in Pet.App. F at 96a-104a (hereinafter "*Ives* V").

JURISDICTION

The judgment of the United States Court of Appeals for the Second Circuit, sought to be reviewed herein, was entered on January 8, 1981. Petitioners' subsequent timely petition for rehearing with suggestion for rehearing *en banc* was denied on February 25, 1981. This Court granted petitioners' request for an extension of time within which to file their petition for a writ of *certiorari* to and including June 25, 1981. The petition for a writ of *certiorari* in Case No. 80-2182 was duly filed on June 24, 1981, and granted on October 13, 1981. 28 U.S.C. §2101(c); Supreme Court Rules, 20.2, 20.4, 20.6 (1981). By order of the Court, the petition was consolidated with Petition No. 81-12 filed on behalf of Darby, Sherry, Rugby and MD. *See* 50 U.S.L.W. 3278 (October 13, 1981).

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The constitutional provisions involved herein are Article I, §8, clause 8 of the Constitution of the United States and the First Amendment to the Constitution of the United States. The

federal statutory provisions involved herein are §§32 and 43(a) of the Lanham Act [15 U.S.C. §§1114; 1125(a)]. The state statutory provisions involved herein are N.Y. Education Law §§6810; 6815(2)(h), (j); 6816; 6816-a (McKinney's Supp. 1981); and N.Y. Public Health Law §206(l)(o) (McKinney's Supp. 1981).

Due to the length of these provisions, they are all reprinted in full in Pet.App. G at 106a-122a.

STATEMENT OF THE CASE

Introduction

This proceeding arises from the opinion of the United States Court of Appeals for the Second Circuit in *Ives* IV, directing the issuance of an injunction against petitioner Inwood and the other petitioners herein [*Ives* IV at Pet.App. 83a, 86a]. The court held that petitioners could not continue to market a drug product identified generically as "cyclandelate" in capsules which are colored either blue or blue/red in 200 and 400-mg. dosages, respectively.

Respondent Ives Laboratories, Inc. ("Ives") markets a cyclandelate drug product under the brand name "CYCLOSPASMOL". Ives claims in this action that, with respect to cyclandelate, it has the exclusive right to these otherwise common capsule colors.

After the Second Circuit had affirmed a denial of Ives' motion for a preliminary injunction, a bench trial was held in the United States District Court for the Eastern District of New York (Nickerson, J.). The trial court rejected all of Ives' numerous factual and legal theories. On the second appeal, however, the Court of Appeals reversed. The reversal was based solely upon what throughout the proceedings had been considered the least significant of all of Ives' claims for relief — that petitioners were liable for "contributory trademark infringement".[1] *See Ives* IV at Pet.App. 86a, n.1 (Mulligan, J., dissenting). It is therefore necessary to review the facts and course of proceedings below in some detail.

1. Ives' complaint mentioned "contributory trademark infringement" only tangentially in the midst of alleging a common-law unfair competition claim (Cont'd)

Parties Hereto and the Nature of their Business

Ives is a pharmaceutical company which manufactures and sells, among other items, a drug product in interstate commerce under the aforementioned brand name "CYCLOSPASMOL". The active ingredient in the CYCLOSPASMOL product is generically identified as cyclandelate.[2] CYCLOSPASMOL is a registered trademark owned by Ives [Pre-trial Order ("PTO"), Stipulated Fact #10, J.A. 34a].

In the trade, Ives is known as a brand-name pharmaceutical house. It heavily promotes and advertises the sale of brand-name drugs, such as CYCLOSPASMOL [Tr. 27a-30a, J.A. 86a-89a].[3] *See also Ives* III at Pet.App. 57a. The focus of its nationwide promotional efforts is to popularize its brand name for a given drug product. These promotional efforts are directed only to physicians, pharmacists and other health professionals [Tr. 64a, J.A. 97a; Tr. 67a, J.A. 98a].[4] Ives employs a nationwide sales force which "details" its brand-name drugs by making personal visits to doctors' offices [Tr. 8B-10B, J.A. 107a-108a]. Doctors are thereby encouraged to recommend and prescribe Ives' brand-

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(Cont'd)

(Complaint, Count II, ¶37, J.A. 21a). "J.A." references are to the Joint Appendix. All J.A. references which refer to the trial record are preceded by a "Tr." page reference indicating where the citation appears in the full record. All J.A. references which refer to exhibits are preceded by an "Ex." and "Tr." page reference in accordance with the form required by Supreme Court Rule 34.3. Other documents in the Record are identified by their docket sheet designation. In accordance with Supreme Court Rule 30.2, some record references are not included in the Joint Appendix.

2. Cyclandelate is a contraction of the chemical name 3,5,5 trimethylcyclohexyl mandelate [*See* Pl.Ex. 7, 8; Tr. 35a, 48a, J.A. 570a-571a]. *See, generally, Abbott Laboratories v. Celebrezze*, 228 F.Supp. 855, 863 (D.Del. 1964), *vacated on other grounds*, 352 F.2d 286 (3d Cir. 1965).

3. It has been estimated that the advertising expenditures of the large drug manufacturers to physicians amount to approximately 24% of every sales dollar. *See* Willig, *The Prosubstitution Trend in Modern Pharmacy Law*, 6 U.MICH.J.L. REFORM 1, 16 (1972). The cost of this advertising is, "of course, reflected in the increased cost of their drugs." *See* Note, *Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws*, 67 KY.L.J. 384, 390 (1978-79) (hereinafter *Consumer Protection*)

4. Drug companies may not advertise prescription drugs to the public. *See, e.g.*, 21 C.F.R. §200.7 (1981).

name drugs to the exclusion of available alternatives. *Ives* II at Pet.App. 31a.[5]

Petitioner Inwood is known in the pharmaceutical trade as a "generic drug manufacturer."[6] This branch of the pharmaceutical industry does not engage in substantial nationwide advertising or promotion through a nationwide sales force [Tr. 657, J.A. 225a; Pl.Ex. 143 at 7, 10, Tr. 109B, 947, J.A. 385a]. Inwood, for example, has three outside agents who call on wholesalers, distributors, large chain stores and hospitals to solicit orders for its drug products [Pl.Ex. 144 at 9-10, Tr. 109B, Tr. 947, J.A. 409a]. These products are not promoted by brand name, but rather are labeled and sold under their generic designation [Tr. 655-656, J.A. 223a-224a; Pl.Ex. 48-60, Tr. 107B-108B, J.A. 586a-652a]. Inwood also solicits its accounts by mailing price sheets which list its available drugs [Pl.Ex. 49, Tr. 107B, 108B, J.A. 609a-618a]. Inwood, like most generic drug manufacturers (including Premo), does not for the most part sell directly to or solicit orders from individual retail pharmacies.[7] The key factor in Inwood's ability to compete with brand-name houses such as Ives is the extent to which generic drugs are accepted in the marketplace on their own merit, rather than on fanciful advertising and promotion. Inwood and other generic drug manufacturers compete against each other in selling generic drug products to distributors and wholesalers [PTO, Stipulated Facts 27-30, J.A. 37a]. Many of the same distributors and wholesalers also purchase drug products from the brand-name companies. Petitioners Darby and Sherry, for example, thus offer both the brand-name product and the generic product to the individual retail pharmacy[8] [Pl.Ex. 50-56, 58-59; J.A. 619a-643a, 647a-651a].

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5. Ives' manner of conducting business is typical of the brand-name drug industry. *Cf., United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1118, 1126 (D.N.J. 1976).

6. Petitioners Premo and MD are also manufacturers. The remaining three petitioners, Darby, Rugby and Sherry, are distributers of generic drug products.

7. As noted by Judge Nickerson, Inwood does sell to some retail accounts [*Ives* III at Pet.App.37a]. These accounts are primarily chain stores, which function as a distributor for a large number of their own individual pharmacies [Pl.Ex.144 at 9-10, J.A. 409a (where no Tr. reference follows an exhibit citation it indicates that such reference has previously been provided)]. *See also A.H. Robins Co. v. Medicine Chest Corp.*, 206 U.S.P.Q. 1015, 1018 (E.D.Mo. 1980) (Finding of Fact #26, noting "Inwood only sells to pharmaceutical distributors.").

8. Petitioner Rugby sells only generic drug products [Pl.Ex. 145 at 23, Tr. 109B, 948, J.A. 425a].

Certain competitive realities in the marketing of brand-name and generic drugs are undisputed.[9] Inwood and other generic companies sell their products for far less than do brand-name companies [Tr. 657, J.A. 225a; Tr. 972-973, J.A. 312a]. *See generally*, Inwood Ex. 6, [Tr. 950, J.A. 795a], Report of New York State Assembly Office of Legislative Oversight and Analysis, *Are Generics Safe?* (June 23, 1978). It is also undisputed that consumers realize savings from the purchase of generic drugs; in fact generic competition after brand-name patent expiration drastically reduces the previous monopoly price structure set during the patent life of a brand-name drug.[10]

Another central fact is that the generic names of pharmaceutical products are generally unfamiliar to the consuming public, and that even pharmacists and physicians are often hard-pressed to identify the generic names of popular pharmaceutical products [Tr. 589-590, J.A. 213a-214a; Tr. 656-657, J.A. 225a; Tr. 816, J.A. 271a; Premo Ex. 63 at 58-59, Tr. 761-762, J.A. 461a]. *See* Note, *Pharmaceutical Trademarks*, 15 TULSA L.J. 327, 342 (1979). Generic drug products are therefore typically identified as equivalents or comparable versions of the well-known brand-name pharmaceuticals [Pl.Ex. 48-60, J.A. 586a-652a]. Finally, it is undisputed that for at least 26 years,[11] it has been the general, if not universal, practice to market generic drug products in the same color as their brand-name counterparts.[12]

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9. For a comprehensive analysis of generic/brand-name drug competition, *see* DRUG PRODUCT SELECTION, STAFF REPORT TO THE FEDERAL TRADE COMMISSION (Bureau of Consumer Protection, Jan. 1979) (hereinafter "FTC STAFF REPORT"). *See also Competition in the Drug Industry:* Hearing Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce (97th Cong., 1st Sess., Mar. 10, 1981).

10. *See Competitive Problems in the Drug Industry:* Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business, at 10,268 (93d Cong., 2d Sess. 1974). *See also* FTC STAFF REPORT at 41.

11. *See also* (for an early example of this practice in the context of a non-prescription product) *Heide v. Wallace & Co.*, 129 F. 649 (D.N.J. 1904), *aff'd*, 135 F. 346 (3d Cir. 1905).

12. Ives' witness, the President of the New York State Pharmaceutical Society, stated that such has been the general practice during his entire 24 years of experience as a pharmacist [Tr. 327, J.A. 176a]. Similar testimony was given by petitioners' witnesses [Tr. 770, J.A. 263a-264a; Pl.Ex. 144 at 22, J.A. 411a;

(Cont'd)

The Impact of Drug Substitution Laws

Unlike most other commodities where trademark or unfair competition issues arise, the ultimate user of the prescription drug plays virtually no controlling role in selecting the product to be purchased: the choice of drug is made by the physician. Ives and other brand-name companies therefore seek to induce physicians to prescribe their product by engaging in extensive brand-name promotion [Tr. 27a-30a, J.A. 85a-88a; Tr. 85a-89a, J.A. 100a-103a]. Central to this marketing strategy is the fact that in all states the law permits physicians to write prescriptions by brand-name. Some 90% of all prescriptions are so written. *See* R.Bond and D.Lean, SALES, PROMOTION AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS, 85, 89 (1977).

At least until the late 1970's, most state laws required that a written prescription for a brand-name product be filled only by dispensing the identified brand. These laws, known as "antisubstitution laws", reached their highwater mark by 1972, when 47 states had laws making it illegal to substitute even chemically equivalent drugs for the particular brand named in the prescription. *Consumer Protection*, 67 KY.L.J. at 389-390. Given this setting, and in light of extensive brand-name promotion, brand-name prescribing has become, and continues to be, the predominant way in which prescription drugs are identified.

Particularly in the case of patented drugs, promotion during the life of the patent virtually obscures the generic chemical name for most prescription pharmaceuticals. Upon patent expiration, the smaller generic competitors are thereby faced with the formidable obstacle of attempting to market a product known to and prescribed by physicians primarily under the former patentholder's brand name. Under the former law of almost all states, the ingrained practice of brand-name prescribing acted as a virtual bar to effective competition, except for the limited number of instances where physicians prescribed

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(Cont'd)

Pl.Ex. 145 at 52, J.A. 431a]. At the hearing on the preliminary injunction, the undisputed evidence was that this practice has been prevalant for at least 40 years [Affidavit of Seymour Blackman in opposition to plaintiff's motion for a preliminary injunction, sworn to May 11, 1978 at ¶14].

generically[13] [Tr. 765, J.A. 262a-263a]. *See also Consumer Protection,* 67 KY.L.J. at 390.

In the mid-1970's, various states began enacting what are commonly known as "drug substitution" statutes. Recognizing that physicians prescribe by brand name, even after patent expiration, due to a lack of familiarity with the generic name, these statutes specify circumstances under which the pharmacist may, and in some states must, dispense a lower-cost generic drug product, even if the physician has identified a brand name on his written prescription. *See, e.g.,* N.Y. EDUC. LAW §§6810; 6815(2)(h), (j); 6816; and 6816-a (Pet.App. at 112a-122a).[14] These statutes do not prohibit brand-name prescribing. Rather, they recognize that the physician's utilization of a brand-name identification may simply be a shorthand description of the active ingredient, without the exercise of any medical judgment or preference that solely the brand-name product be utilized.

The enactment of drug substitution laws by 49 states, the District of Columbia and Puerto Rico, was accomplished despite

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13. "It is understandable that physicians do and will continue to prescribe by brand name . . . It's easier and quicker. Most drug products have three names. Take Librium. It has a chemical name intelligible only to accomplished organic chemists, not pronouncable here; a generic name— chlordiazepoxide hydrochloride; and then a tradename which, if registered, can be used exclusively. What busy physician wouldn't prefer a tradename such as Librium to the generic." *FDA Drug List: Key to Generic Substitution,* FDA CONSUMER (Feb. 1979) at 17. [*See also* Tr. 589-590, J.A. 213a]

14. For a comprehensive analysis of the drug substitution laws, *see Consumer Protection,* 67 KY.L.J. at 395-407. For an updated compilation, *see* National Association of Board of Pharmacy Survey of Pharmacy Law (1981-82) at 27-28. The format for these statutes varies from state to state. In many, the law is permissive in nature, *i.e.,* the pharmacist is permitted, usually with the patient's consent, to dispense a less-expensive generic product. In some states, as in the case of New York, generic dispensing is mandatory if the product in question and its generic manufacturer are listed in an approved state formulary. Most states require that written prescriptions be on a form which contains two lines for the physician's signature. The physician indicates whether substitution is permissible or impermissible by signing his name on the appropriate line. (In New York, otherwise mandatory substitution becomes "permissible" if the product is not listed in the official formulary. *See Ives* IV at Pet.App. 77a, n.5). In other states, generic dispensing is automatically authorized unless the physician indicates to the contrary by affirmatively writing on the prescription such terms as "dispense as written" or "no substitution."

the vigorous opposition of the brand-name companies.[15] The impact of the generic substitution laws on the more than 8 billion dollar prescription drug market is therefore clear.[16] After a patent expires, brand-name drug companies can no longer rely on the fact that prescribing physicians are unfamiliar with the generic names of the drug products which they prescribe. They must instead seek to persuade the prescriber to affirmatively insist on the brand name by indicating on the prescription forms that substitution is impermissible, or that the prescription should be dispensed as written. *Ives* II at Pet.App. 31a.

The Course of Proceedings Below

Cyclandelate, a prescription drug product, has been marketed as a vasodilator for use in the treatment and management of peripheral and cerebral vascular diseases[17] [PTO, Stipulated Fact #19, J.A. 36a]. It is not used to cure any disease; rather its action is for the purpose of inhibiting the otherwise progressive and debilitating effects of the indicated conditions, which generally occur in the elderly [Tr. 43a, J.A. 94a; Tr. 859, J.A. 286a]. Once prescribed, and assuming the physician is satisfied with the therapeutic effect, the use of this drug necessarily becomes long-term and continues for the duration of the patient's lifetime [PTO, Stipulated Fact #19, J.A. 36a]. By reason of the nature of their conditions, patients taking cyclandelate are often disoriented and subject to emotional fears and stress [Tr. 859, J.A. 286a].

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15. *See* Haddad, *Generic Drugs — Tomorrow's Market*, 33 FOOD, DRUG & COSM.L.J. 488, 489 (1978). *See also Pharmaceutical Mfrs. Ass'n v. Kennedy*, 471 F.Supp. 1224 (D.Md. 1979); *Pharmaceutical Society of New York, Inc. v. Lefkowitz*, 586 F.2d 953 (2d Cir. 1978); *Pharmaceutical Mfrs. Ass'n v. Whelan*, ___ Misc.2d ___, Index No. 15831/78 (Sup.Ct.N.Y.Co., Aug. 15, 1980), *aff'd without opinion*, 79 A.D.2d 876, 435 N.Y.S.2d 618 (1st Dept., Dec. 4, 1980), *appeal pending* (attacking generic substitution law as unconstitutional, promoting trademark infringement and unfair competition, and depriving brand-name companies of due process).

16. *See generally*, FTC STAFF REPORT at 25-28. *See also* SRI International, *Pharmaceutical Industry Perspectives: A U.S. Generics Breakthrough?* (May 1980).

17. Its rationale for use under these conditions is that upon ingestion there is an increase in the blood flow of otherwise-constricted peripheral blood vessels. It is indicated as adjunctive therapy in such conditions as intermittent claudication, arteriosclerosis obliterans, thrombophlebitis (to control associated vasospasm and muscular ischemia), nocturnal leg cramps, Reynaud's phenomenon, and for selected cases of ischemic cerebral vascular disease [Pl.Ex. 11, Tr. 29a-31a].

Since 1958, Ives has sold cyclandelate as a heavily promoted brand-name product known as "CYCLOSPASMOL". By 1962, Ives was marketing two CYCLOSPASMOL dosage forms; an orange, 100-mg. tablet,[18] and a blue, 200-mg. capsule. Until April 26, 1972, Ives was immune from competition in the United States for its cyclandelate product by virtue of a patent which had been issued to its predecessor-in-interest [*Ives* II at Pet.App. 31a]. In 1975, Ives began marketing a 400-mg. dosage form of cyclandelate in a blue/red capsule. Blue and blue/red capsules as such are not unique or distinctive in the pharmaceutical trade [*See, e.g.*, Tr. 596, J.A. 218a; Pl.Ex. 137, Tr. 939 — *Physician's Desk Reference*, Product Identification Section at 434 for E.R. Squibb's VELOSEF product]. Ives has never applied for registration of either color configuration as a trademark, copyright or design patent. Ives imprints its name and an accompanying identifying number of both the 200-mg. and 400-mg. dosage forms.

Despite its long history of use, the efficacy of cyclandelate for its intended purposes remains in doubt. As part of the historic DESI review conducted by the FDA,[19] cyclandelate was found lacking in efficacy for some of its indications and only possibly effective for others [Pl.Ex. 11, Tr. 29a, 48a]. FDA has since proposed that cyclandelate be withdrawn from the market, and that Ives' prior approval to market CYCLOSPASMOL be revoked. 44 F.R. 30436-37; 30443-46 (May 25, 1979) [Inwood Ex.7, Tr. 950; *see also* Tr. 92B, J.A. 122a-123a]

The foregoing is relevant in two respects. First, efficacy questions have prevented the listing of cyclandelate in certain state formularies, with the result that substitution in such states as New York is permissive, rather than mandatory. *See Ives* IV at Pet.App. 77a, n.5. Second, the possible lack of efficacy raises the distinct possibility that the primary, if not entire, effect of cyclandelate is due to its function as a placebo. For an example of a widely prescribed drug being classified as a placebo, *see Mead Johnson & Co. v. Premo Pharmaceutical Laboratories, Inc.*, 207 U.S.P.Q. 820, 826 (D.N.J. 1980) [finding of fact #136]. It is undisputed that the placebo effect can play an important role, even for medications which are considered

18. The tablet is not at issue in this litigation.

19. *See Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 614-615 (1973).

therapeutically effective. [*See* Tr. 57B, J.A. 118a-119a; Tr. 414-415, J.A. 195a-196a]

In 1976, Inwood commenced manufacturing and marketing a generic cyclandelate product to compete with CYCLOSPASMOL [Pl.Ex. 144 at 20, J.A. 410a]. Inwood marketed its cyclandelate product to its wholesaler and distributor accounts in exactly the same way that it and other generic companies have marketed their products for the last 40 years. Inwood sold its 200-mg. dosage form in a blue capsule and its 400-mg. dosage form in a blue/red capsule, *viz.*, the same colors previously used by Ives. As with other products, Inwood's cyclandelate was listed on the price sheets it distributed [Pl.Ex. 49, J.A. 609a]. These sheets merely identified the generic name, color and price of Inwood's product. A separate column identified the brand-name product to which each generic product corresponded.[20]

At trial, Ives' witnesses admitted that it had known of the competitive marketing by Inwood from its very inception [Tr. 69a, J.A. 98a-99a]. This lawsuit, however, was not commenced until more than two years later—Feb. 28, 1978.[21] By this time, the nationwide sweep of the movement towards "drug substitution" was almost complete. Also underway was a widespread effort by brand-name manufacturers, seeking to reverse the historical trend by which generic drug products were marketed in colors similar to the brand-name products.[22]

Thus, on the eve of the effective date of the New York substitution law (April 1, 1978), Ives commenced the instant case against the petitioners. One individual retail pharmacy located in New York State was also included as a defendant. Ives alleged, *inter alia*, that this pharmacy (Lowitt Labs, Inc.) had filled two

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20. This innocuous document [Pl.Ex. 49] ultimately became the key factor in the finding that Inwood was liable as a contributory trademark infringer. A replication of this document is set forth in the Joint Appendix [J.A. 609a-618a].

21. Ives asserted that it had only "gradually" become aware of the injury supposedly being caused by the sale of generic cyclandelate products [Tr. 69a, J.A. 99a].

22. The first of these appears to have been *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 786 (3d Cir. 1978). The instant case is the first of a series of essentially contemporaneous lawsuits against generic companies to reach this Court. *See* discussion at Point II, *Infra*.

prescriptions for CYCLOSPASMOL by dispensing a generic version thereof [Complaint ¶47-52, J.A. 23a-24a]. The pharmacy and Ives promptly entered into a consent decree under which the pharmacy admitted having committed the acts complained of, and consented to an injunction against any unlawful substitution [J.A. 29a].

Ives also alleged: (a) one trademark infringement count against petitioner Sherry;[23] (b) an unfair competition count claiming that petitioners' use of similar capsule colors violated Ives' proprietary rights; (c) a claim under §43(a) of the Lanham Act [15 U.S.C. §1125(a)] that petitioners had engaged in false advertising by claiming their generic cyclandelate products as equivalents of Ives' CYCLOSPASMOL;[24] and (d) that petitioners' actions violated §368-d of the New York State General Business Law.

Ives moved for a preliminary injunction primarily on the grounds that the use of identical capsule colors constituted a *per se* violation of both §43(a) of the Lanham Act, and the New York State law of unfair competition. Ives further claimed that petitioners were liable for "contributory trademark infringement." Relying upon *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., supra,* Ives contended that mere copying of capsule colors was enough to establish "secondary meaning" and its exclusive right to blue and blue/red colors.

The District Court denied the motion (*Ives* I), and the Second Circuit affirmed (*Ives* II). The Second Circuit rejected Ives' claim that secondary meaning could be established by showing merely that the capsule colors in question had been copies (*Ives* II at Pet.App. 50a-51a). It held that Ives would have to establish that consumers had come to associate the capsule colors as indicating a particular source of origin. Further, referring to the evidence of functionality described by Judge Nickerson in *Ives* I at Pet.App. 22a-24a, the Court of Appeals

23. The complaint's only reference to statutory trademark infringement is not at issue here. Sherry had discontinued the name "SPASMOL" for its cyclandelate. *Ives* I at Pet.App. 7a.

24. This claim was not supported at trial by any evidence, *Ives* III at Pet. App. 62a, and was abandoned on appeal. *Ives* IV at Pet. App. 86a, n.1 (Mulligan, J., dissenting).

noted that such evidence, if confirmed at trial, would defeat Ives' claim under §43(a) (*Ives* II at Pet.App. 48a-51a).

In support of its motion, Ives introduced evidence consisting of 15 test-shoppings where Ives personnel presented prescriptions to one pharmacy in Mississippi, one pharmacy in Pennsylvania, two pharmacies in New York, and five pharmacies in Michigan [Pl.Ex. 95-107, Tr. 248-249, J.A. 732a-782a]. These locations were selected because Ives suspected that the pharmacists in question were "bad actors" having a proclivity towards illegal substitution [PTO, Stipulated Fact #25, J.A. 37a]. Ives claimed that its suspicions were confirmed by the results of these test-shoppings and that these pharmacies had unlawfully substituted a generic brand where the prescription had called for CYCLOSPASMOL.[25]

Judge Friendly's opinion in *Ives* II held that this sparse evidence was not enough to make the petitioners vicariously liable for the acts of the few supposedly unscrupulous pharmacists. He found that Ives had shown only that similarity of capsule colors had made it easier for a druggist, already inclined to engage in unlawful conduct, to do so. *Ives* II at Pet.App. 36a. At trial, Ives would have to show that petitioners had "suggested, even if only by implication", that pharmacists engage in conduct which infringed Ives' trademark, and that such conduct was "much more widespread" than suggested by the meager evidence introduced by Ives below. *Id.* at Pet.App. 35a, 52a-53a.

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25. Actually, the Michigan test-shoppings were not examples of "illegal substitution." Michigan had already enacted a drug substitution law. MICH. COMP. LAWS ANN. §338.1114a (Supp. 1975-76). The prescriptions in question had not specified "dispense as written," and the pharmacist, under the law, was thus entitled to dispense the generic, rather than the brand-name drug. *Id* at §338.1114a(3)(b). *See* Note, *Improving Michigan's Generic Drug Law*, 9 MICH. J.L. REFORM 394, 402 (1976). Significantly, three of the Michigan pharmacists clearly labeled the product dispensed as the equivalent product of another manufacturer of cyclandelate, *e.g.*, "Premo Equivalent" [*see* Pl.Ex. 95, 98, 102, J.A. 732a, 744a, 760a]. Although these pharmacists used the name "Cyclospasmol," it has been noted that the early Michigan statute had engendered serious confusion among pharmacists. *Id.*, Note at 400-401. *See also Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F.Supp. 413, 422 (E.D.Mich. 1979), *appeal dismissed*, 615 F.2d 1362 (6th Cir. 1980).

The "Additional Evidence" Produced By Ives

At trial, Ives did not attempt to show any further evidence of "illegal substitution" beyond that already found in *Ives* II to be insufficient to support a finding of contributory infringement.[26] Accordingly, at trial, Ives did not contend that "illegal substitution" for CYCLOSPASMOL was any more widespread than the original 15 instances which had been adduced in connection with the motion for a preliminary injunction [Tr. 85-86, J.A. 145a; Tr. 394]. In fact, Ives' own witness, the Executive Director of the New York State Pharmaceutical Society, further testified that "illegal substitution" was, in fact, not widespread [Tr. 352-353, J.A. 182a][27]. Attempting nevertheless to satisfy the Second Circuit's standard regarding contributory trademark infringement,[28] Ives conducted a survey intended to show that instances of *lawful* substitution under the New York State drug substitution law might produce instances of trademark infringement. To this end, Ives surveyed 83 pharmacies in New York State, 42 of which were selected by Ives personnel and 41 of which were selected at random from a directory of New York State pharmacies. Ives' test-shoppers presented a prescription to these pharmacists, which mentioned CYCLOSPASMOL, and was signed on the line of the New York prescription form affirmatively noting "substitution permissible" [Pl.Ex. 83, Tr. 83, 92, J.A. 354a].

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26. The evidence showed that a survey could have easily been done to reveal the extent of "illegal substitution," if any, with respect to CYCLOSPASMOL [Tr. 567-568, J.A. 205a]. Ives expressly advised the Court that it would not undertake to do so [Tr. 86, J.A. 145a; Tr. 394; *see also* Tr. 120a, J.A. 106a-107a].

27. See also *Ives* IV at Pet.App. 89a, n.2 (Mulligan, J., dissenting).

28. "The authorities later reviewed by us indicte that a manufacturer or wholesaler would be liable under §32 if he suggested even if only by implication that a retailer fill a bottle with generic capsules and apply Ives' mark to the label or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described." *Ives* II at Pet.App. 35a-36a.

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"Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Ives* II at Pet.App. 53a.

A total of 35 pharmacists in this limited survey[29] *lawfully* dispensed a generic product[30] [Tr. 85-86, J.A. 145a]. Of these, 10 included the word "CYCLOSPASMOL" in some fashion on the label of the dispensing container. Five of this latter group labeled the product as follows:

> "Generic Cyclospasmol" [Pl.Ex. 82-000, J.A. 691a;[31] Pl.Ex. 82S, J.A. 695a[32]].
> "Cyclospasmol Generic" [Pl.Ex. 82E, J.A. 699a; Pl.Ex. 82SSS, J.A. 703a].
> "Cyclospasmol Gen (Spencer Mead)" [Pl.Ex. 82TTT, J.A. 707a]. [All bottles which make up Exhibit 82 were offered into evidence at the same time. (Tr. 85-86, 92)]

Of the remaining five, two pharmacists appeared to have listed the name of the manufacturer, as required under New York law, *viz.*, "Cyclospasmol 400mg. (Rugby)" [Pl.Ex. 82BB, J.A. 711a][33] and "Hylan: Cyclospasmol" [Pl.Ex. 82A, J.A. 715a]. The other three [Pl.Ex. 82DDD, J.A. 726a; 82 HHH, J.A. 723a; 82T, J.A. 719a] listed only the name "Cyclospasmol". Thus, a total of seven pharmacists wrote the term "generic" either on the label or on a receipt and/or listed the name of the generic manufacturer. All of the pharmacists except one either spontaneously or in response to an inquiry expressly informed the customer that the generic product had been dispensed. For example, as indicated by Pl.Ex. 82BB, J.A. 712a, the pharmacist informed the patient orally, "[T]he generic was dispensed on account of its lower cost." *See also* Pl.Ex. 82S, J.A. 696a, where the pharmacist told

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29. As observed by Judge Mulligan, the shopping of 83 pharmacies in one state (half of which were selected by Ives under circumstances which are at best unclear) had no statistical validity, *Ives* IV at Pet.App. 87a, 89a. An expert testified that this survey was "winged casually" and contained "figures engineered with their basis to inflate them in a way that would be misleading."[Tr. 640-643, J.A. 222a-223a].

30. The balance dispensed the brand-name product because they either did not have the generic product available or erroneously believed that a generic product could not be dispensed.

31. This pharmacist also listed the name of the generic manufacturer.

32. This pharmacist applied a label stating, "[A] generic equivalent drug has been dispensed of the same quality and at a lower price."

33. In addition, this pharmacist gave the customer a receipt expressly stating that a generic had been dispensed.

the customer that CYCLOSPASMOL was three times more expensive than the generic. This was consistent with the practice of many other pharmacists in the survey who dispensed the generic and emphasized the cost-savings to customers. (*See* Pl.Ex. 82-000; 82L; 82W; 82X; 82VVV; 82XXX.) As found by Judge Nickerson, *Ives* III at Pet.App. 60a, and noted by Judge Mulligan in his dissent, *Ives* IV at Pet.App. 88a, only one pharmacist "appeared" to have charged a brand-name price.[34]

The *Ives* II opinion had directed that petitioners could be liable for contributory infringement only if they suggested to pharmacists, even by implication, that they infringe Ives' trademark, or if petitioners continued to sell to a pharmacist whom they knew were infringing the trademark. On the latter score, Ives introduced no evidence, and did not claim below that any of the petitioners continued sales to a pharmacist whom they knew or should have known was engaged in illegal substitution or mislabeling. *Ives* III at Pet.App. 59a. *See also Ives* IV at Pet.App. 87a-88a (Mulligan, J.). Instead, Ives sought to satisfy the "suggestion by implication" prong of the standard established in *Ives* II by introducing various catalogs and promotional materials disseminated by petitioners. Ives claimed that by way of these materials, petitioners "suggested by implication" that pharmacists mislabel lawfully dispensed generics as CYCLOSPASMOL.

In the case of Inwood, these "catalogs" consisted solely of price sheets listing various drug products, including cyclandelate [Pl.Ex. 49, J.A. 609a-618a]. The price sheets, under appropriate column headings, list (1) the name of the equivalent brand-name product, (2) the generic description of the product available from Inwood, (3) the strength of each drug, (4) the color of each dosage form, and (5) Inwood's price. Cyclandelate is in no way singled out by the price sheet or by any catalogs distributed by the other petitioners.

Inwood's price sheets were distributed only to its wholesaler, distributor, chain store and hospital accounts [Pl.Ex. 144 at pp. 9-10, J.A. 409a]. Ives introduced no evidence that any

34. An additional survey of 25 pharmacies showed that when lawful substitution occurred, 23 pharmacists labeled the container as cyclandelate without reference to CYCLOSPASMOL, and 2 pharmacists labeled it as "Cyclopasmol Generic" [Pl.Ex. 142, Tr. 957, J.A. 375a-382a].

retail or dispensing pharmacist had seen the price list.[35] As a matter of evidence, there was thus no possible basis for a finding that Inwood or the other two manufacturer-petitioners had actually or impliedly suggested anything to any pharmacist.[36]

Ives also introduced the catalogs of the wholesaler petitioners [Pl.Ex. 50-59, J.A. 619a-652a]. In the case of Darby, which sells both the Ives CYCLOSPASMOL brand and generic cyclandelate, one section of the catalog advertised the availability from Darby of both brand-name and generic products. Cyclandelate is one of the products listed in this section. Darby's prices for cyclandelate and Ives' CYCLOSPASMOL are listed; no reference is made to color [Pl.Ex. 50 at p. 4, J.A. 622a]. Other sections of Darby's catalog list generic and brand-name products and their prices separately [*Id.* at p. 3, J.A. 621a]. In the generic listing, products are identified as a generic for the brand-name, and the color of Darby's product is noted.[37] Although the catalogs of the wholesaler petitioners are distributed to pharmacists, it is difficult to understand how these catalogs constituted an implied suggestion to pharmacists to engage in illegal conduct.[38]

The Role of Capsule Colors for Prescription Drugs

The uncontradicted evidence below established that a change in the color of a prescription pharmaceutical plays an important role in the patient's initial reaction to the drug

35. There was no such evidence for any of the other manufacturer's price lists as well.

36. Petitioner MD's "catalog" was similarly only a product list which, moreover, did not contain any color references [Pl.Ex.60, J.A. 652a].

37. Sherry's catalog was similar, except that cyclandelate and CYCLOSPASMOL were not listed side by side, but rather separately at their respective alphabetic positions [Pl.Ex. 51 at pp.2-3, J.A. 624a-625a]. As already noted, Rugby sells only generic drugs. Its catalog includes a chart identifying which of its generic products correspond to the national brand and a separate section where the price of the generic product (but not CYCLOSPASMOL) is listed [Pl.Ex. 57 at p.3, J.A. 646a].

38. Since Judge Mansfield's discussion does not accurately describe any of the catalogs, we respectfully ask this Court to examine these catalogs in order to assess what significance, if any, they have on the issue of contributory trademark infringement.

product after it is dispensed. Some of the strongest evidence in this respect came from Ives. In its unsuccessful attempt to prove that the blue and blue/red capsule colors have a secondary meaning, Ives established that for patients taking CYCLOSPASMOL, the color of the product is central to the patient's identification of their medication.[39] The Ives survey on secondary meaning, for all its deficiencies,[40] showed that 79% of patients surveyed identified the capsules presented to them by their color alone [Pl.Ex. 74 at 7, Tr. 70-72, 92, J.A. 332a]. No one disputed the result of an unexplained change in capsule color: it was agreed that virtually all patients would believe that a mistake had been made in filling their prescription in the absence of a prior explanation by the pharmacist or dispensing physician [Tr. 62a-63a, J.A. 96a; Tr. 37B, J.A. 111a; Tr. 51B, J.A. 116a; Tr. 311, J.A. 172a; Tr. 316, J.A. 173a; Tr. 353, J.A. 182a-183a; Tr. 577, J.A. 206a; Tr. 582, J.A. 210a-211a; Tr. 667-668, J.A. 230a; Tr. 687, J.A. 233a-234a; Tr. 691, J.A. 236a; Tr.

39. As the Vice President of Ives stated in his affidavit in support of Ives' motion for a preliminary injunction at ¶18:

> "[T]he patient receiving his prescription for CYCLOSPASMOL cyclandelate capsules relies on their distinctive appearance to assure himself that they are the same capsules which he has previously taken. In the case of CYCLOSPASMOL, the patient rapidly becomes familiar with the distinctive color of Ives' cyclandelate capsules because . . . the treatment and management of peripheral vasodilator disorders takes place over an extended time period, requiring at least months and in some cases years of continuous treatment. In fact, practically 100% of the patients on cyclandelate treatment are repeat users. Therefore, patients taking Ives' CYCLOSPASMOL cyclandelate are continuously and for extended time periods exposed to the color of the 200 mg. and 400 mg. CYCLOSPASMOL capsules. This extended exposure leaves the patient with a strong visual picture of the appearance of the product he is taking and he relies upon the appearance of the product as assurance that he is always receiving the same identical product that his physician prescribed." *See* Affidavit of Herbert Lowenkron, sworn to March 2, 1978.

Mr. Lowenkron confirmed his affidavit statements at trial [Tr. 62a-63a, J.A. 96a].

40. The survey was plagued with significant difficulties of execution. Statistical projectibility was completely compromised by the fact that only a 20% response rate at the initial level could be obtained [Tr. 610-613]. *See generally*, 1-Part 2 MOORE'S FEDERAL PRACTICE at 123-157 (2d Ed. 1979).

708-709, J.A. 246a; Tr. 734-735, J.A. 249a; Tr. 748, J.A. 257a; Tr. 775, J.A. 265a; Tr. 868-872, J.A. 291a-294a].

Further, many patients associate the appearance of a medication with its therapeutic effect[41] [Tr. 578, J.A. 207a; Tr. 684, J.A. 231a; Tr. 774, J.A. 264a; Tr. 865, J.A. 289a; Tr. 878, J.A. 299a]. Some patients accept a pharmacist's explanation that a color difference results merely from a change in brand. Many, however, refuse to accept their pharmacist's explanation and insist on contacting their physician [Tr. 690-691, J.A. 236a; Tr. 735-736, J.A. 250a; Tr. 975, J.A. 313a]. Thus, some patients may eventually accept changes in color, but only after having experienced considerable anxiety and confusion. *Ives* III at Pet.App. 63a. Finally, there was extensive testimony that some patients refuse to accept equivalent drugs, even after all explanation, solely because of differences in color [Tr. 581-583, J.A. 209a-211a; Tr. 695, J.A. 238a; Tr. 735-736, J.A. 250a; Tr. 826-827, J.A. 277a].

The problem of anxiety and confusion is particularly important in the case of a maintenance drug such as cyclandelate, where the patient, by reason of his or her long period of use, becomes strongly accustomed to a single appearance [Tr. 579, J.A. 208a; Tr. 698-699, J.A. 240a; Tr. 734, J.A. 249a; Tr. 869, J.A. 292a-293a]. There was testimony that on occasion doctors insist on a specific brand for institutionalized patients solely because they wish to avoid an anxiety producing color change [Tr. 828-829, J.A. 278a]. Elderly patients are particularly apprehensive, and even frightened, by changes in color of their medication [Tr. 582, J.A. 206a; Tr. 695, J.A. 238a; Tr. 734, J.A. 249a; Tr. 870-871, J.A. 292a-293a].

Uniformity of color was considered critical in institutional settings where a central pharmacy must dispense medications to numerous patients without the benefit of immediate container labeling at the point where each patient receives the product [Tr. 823-826, J.A. 274a-277a]. It was shown that one manufacturer who attempted to sell cyclandelate in a color different from that marketed by Ives was forced to discontinue the product within a

41. Such descriptions as "my red heart pill" or "blue stroke pill" are common [Tr. 578, J.A. 207a; Tr. 734, J.A. 249a; Tr. 865, J.A. 289a. *cf.*, Tr. 488, J.A. 116a; Tr. 318, J.A. 173].

year after its introduction when its hospital clientele refused to accept it precisely because of the color difference [Tr. 830-831, J.A. 279a-281a; Pl.Ex. 144 at 28-29, 66-68, J.A. 412a, 417a-418a]. The Chief Pharmacist of one such hospital testified that, in making decisions on which generic products to purchase, he first tried to ascertain whether the generic is available in the same color as its brand-name counterpart [Tr. 835, J.A. 282a].[42]

The significance of color also extends beyond the point where the product is first dispensed. Patients taking multiple medications, as do many elderly, frequently comingle various drugs in a single container.[43] These patients rely on color to identify the time and frequency for taking their medications [Tr. 54B, J.A. 118a; Tr. 739, J.A. 253a; Tr. 864-865, J.A. 288a-289a]. Even without comingling, physicians in instructing their patients on occasion specify regimens with specific reference to color [Tr. 737-738, J.A. 251a-252a; Tr. 870, J.A. 292a]. *See also Ives* III at Pet.App. 63a.

Changes in color among different brands for the same product are thus a certain source of confusion, anxiety and potential danger for these patients [Tr. 576, J.A. 206a; Tr. 862, J.A. 288a]. Moreover, in emergency situations, where every possible clue must be used in quickly determining or at least estimating which drug an overdose victim has ingested, color, to the extent feasible, was shown to be a valuable aid [Tr. 583-584, J.A. 211a-212a; Tr. 695-696, J.A. 238a-239a, Tr. 742, J.A. 254a; Tr. 874-877, J.A. 296a-298a]. *See also Ives* III at Pet.App. 63a.

Colors serve to identify different dosage strengths of the same therapeutic entity. Ives uses different colors to identify the 200-mg. and 400-mg. dosages, respectively. Ives admitted that for this, as well as its other drug products, color performs this valuable identification function [Tr. 21a, J.A. 83a; Tr. 52a, J.A.

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42. Although it is no longer a general practice, at least one state (New Jersey) required all bidders for cyclandelate procurement contracts to offer the product in blue and blue/red colors [Inwood Ex.11, Tr. 978-980, 986, J.A. 833a].

43. There is extensive testimony that this is done despite the recommendation of doctors that it is not a desirable practice [Tr. 53B-54B, J.A. 117a-118a; Tr. 319, J.A. 174a; Tr. 576-580, J.A. 205a-209a; Tr. 685, J.A. 231a-232a; Tr. 739, J.A. 252a; Tr. 864, J.A. 289a; Tr. 865, J.A. 290a].

95a-96a; *see also* Tr. 832-833, J.A. 281a-282a; Tr. 883, J.A. 301a].[44]

As noted previously the placebo effect for a drug which, like CYCLOSPASMOL, may be of only marginal effectiveness, is of great significance. One of Ives' principal witnesses acknowledged that the placebo effect is often even stronger than the actual pharmacological effect [Tr. 415a, J.A. 195a]. It is undisputed that changes in color can significantly alter the placebo effect for a given patient [Tr. 57B, J.A. 118a-119a; Tr. 414-415, J.A. 195a].[45] The scientific literature shows that specific color configurations are directly related to psychological efficacy of a given drug product *i.e.*, green being preferred for anxiety, yellow for depression, etc.[46]

The District Court's finding of functionality of the capsule colors was therefore firmly rooted in the evidence.[47] If generic

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44. At the hearing on a preliminary injunction, it was shown that one company prominently advertised its various dosage strengths: "No other antidepressant offers SIX TABLET STRENGTHS EACH WITH ITS OWN COLOR. . . . An important feature: The six tablet strengths which makes ELAVIL (Amitryptaline HCL, MSD) so versatile are color coded to facilitate identification and help accurate dispensing." *See* Ex.3 to the Affidavit of Seymour Field in opposition to plaintiff's motion for preliminary injunction, sworn to May 11, 1978. *But cf.*, Judge Biunno's varying, if not novel, discussion of the same evidence in *Biocraft Laboratories, Inc. v. Merck & Co., Inc.*, ___ F.Supp. ___, Civ. Action No. 77-693 at 17-18 (D.N.J. Oct. 2, 1980).

45. This Court has taken note of the well-established fact that identity of appearance is an essential aspect of the placebo effect. *See Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. at 635 (Appendix). *See also Warner-Lambert Co. v. FTC*, 562 F.2d 749, 754, n.9 (D.C.Cir. 1977), *cert. denied*, 435 U.S. 750 (1978).

46. *See, generally*, Schapira, et al., *Study on the Effects of Tablet Colour in the Treatment of Anxiety States* (1970) BRIT. MED J. 2:446-449; A. Leslie, *Ethics and Practice of Placebo Therapy*, 16 AM.J.MED. 854, 859 (1954); D.S. Trouton, *Placebos and Their Pschycological Effect*, 103 J.MENTAL SCI. 344 (1957); S. Dichter, *Handbook of Consumer Motivations*, 228 (1964); C.W. Gowdy, J.T. Hamilton and R.B. Philip, *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise*, 96 CAN.MED. ASS'N J. 1317, 1320 (1967). *See also Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569, 572 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); 3 R. Callman, UNFAIR COMPETITION §82.1(m) at 196 (Supp. 1980). (hereinafter "CALLMAN")

47. Significantly, courts outside the United States have recently made findings virtually identical to those of the District Court. *See Boots Co. Ltd.*

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companies are required to introduce their product in a color different from that of the brand-name company, it will, in the hands of the ultimate consumer, be regarded in the first instance as a mistake [Tr. 699, J.A. 240a]. The generic company's product is therefore placed at the discretion of pharmacists and physicians in terms of their ability to effectively convince patients that the color differences should not affect therapeutic efficacy. A requirement for use of a different color on an equivalent drug thereby places a burden on the marketing of the generic company's product which is not present in the case of the brand-name product. The end result is that color, because of its special role in the eyes of the patient, becomes a factor in the decision of the patient to take a product, the decision of the physician to prescribe a product, and the decision of institutions such as hospitals to purchase the product.[48]

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v. Approved Prescription Services, Ltd., [1980] ___ Ch. ___, B.No. 140 (Unreported: Martin Meredith) (Ch. Div'l. Ct. March 6, 1980), *aff'd*, [1980] B. No. 140 (Unreported: Association) (Court of Appeal Civ. Div. March 28, 1980):

> "There is a good deal of evidence which shows that in connection with other drugs different manufacturers do use exactly the same shape and colour or shapes and colours which are, to a fair approximation, the same; and the reason why they do so is because apparently, if patients have been used in treatment to a pill or capsule of a particular shape and colour, even if the pill they are then offered is a pill containing exactly the same ingredients in a similar formulation, they are not prepared to accept it if the size, shape and colour are different, this being in a sense a purely psychological blockage as far as the patient is concerned."

See also Roche Products Ltd v. Berk Pharmaceuticals, Ltd., [1973] RPC 473 (Supreme Court of Judicature).

48. It should be noted that part of the opposition to enactment of drug substitution laws was based in part on contentions that patients would be subject to anxiety and stress as a result of potential changes in color:

> "Also, as there is always a certain amount of apprehension about taking medications, even those prescribed by a trusted physician, imagine the problems that would be created when the blood pressure pills are one month pink and the next month white and when those that were round one month are the next month rectangular, square or octagonal. The anxiety produced by repeated exposure to unfamiliar size, shape, and color would be sufficient to cause some people to discontinue their treatment program either in whole or in part. I need not detail the damage and even deaths that would result as a consequence of this particular problem." Testimony of

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As pointed out in Department of Health and Human Services, GUIDE TO PRESCRIPTION DRUG COSTS; HCFA-02104 (April, 1980):

> "The FDA proposes to consider products as therapeutically equivalent if they meet the policies outlined in this document, even though they may differ in certain other characteristics, e.g., color, flavor, packaging, expiration date and minor aspects of labeling. When such differences are important in the care of a particular patient, it is appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity." *Id.* at 159.

It may be fairly said, as Judge Nickerson found, that identity of color is an important ingredient in the commercial success of the marketing of generic drug products. *See Ives* III. *See also Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952), *accord, Ives* II at Pet. App. 49a-50a.

The Ruling of the District Court After Trial

The District Court rejected Ives' principal claim under §43(a) of the Lanham Act. It held that the functionality of capsule colors for pharmaceutical products precluded the monopoly which Ives was seeking to establish, and that in any event Ives failed to show that its capsule colors had developed secondary meaning of a single, albeit anonymous, source to the patients who received the medication.[49] In fact, the court found

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> Lawrence A. Tilis, M.D., *Prescription Drug Labeling and Price Advertising*, Hearings Before the Subcomm. on Consumer Protection and Finance for the House Comm. on Interstate and Foreign Commerce at 176 (94th Cong., 2nd Sess. April 22, 1976).

49. In fact, it was almost impossible for Ives to demonstrate secondary meaning as of the late date it conducted its survey, *see Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F.Supp. 762, 769 (E.D.Mich. 1972), *aff'd without opinion*, 473 F.2d 910 (6th Cir. 1973). By that time, approximately 22 companies were manufacturing and/or distributing cyclandelate in the same colors as those used by Ives [*See* Inwood Ex.12, Tr. 955, J.A. 444a, and *Ives Laboratories, Inc. v. Bioline Laboratories, Inc., et al.*, Civ. Action No. 81-914 (D.N.J., Complaint filed Mar. 3, 1981)]. It was not true that the colors

(Cont'd)

that patients regarded the name "CYCLOSPASMOL" as a generic description of the product, rather than as a brand name. *Ives* III at Pet.App. 67a-68a.

On the issue of contributory trademark infringement, the district court noted that Ives had failed to introduce any additional evidence of "illegal substitution" beyond that already found insufficient in *Ives* II. The trial court also rejected the "additional evidence" submitted by Ives showing so-called "mislabeling" during instances of lawful substitution. The Court found that the "mislabeling" had not been shown to have been induced by petitioners; that with only one exception, no pharmacist had intended to profit from the listing of the word "CYCLOSPASMOL" on the label of the lawfully dispensed generic substitute; and all but one pharmacist had actually told the customer that the product was a generic version. The court concluded that the evidence hardly justified an inference that defendants had impliedly invited druggists to "mislabel".[50]

SUMMARY OF ARGUMENT

I.

A. Petitioner Inwood was held liable for "contributory trademark infringement" under Section 32 of the Lanham Act. However, there was no "trademark infringement" for which petitioner could be held liable as a contributor. A few pharmacists were shown by a survey (of dubious statistical relevance) to have *lawfully* dispensed the generic product cyclandelate, and to have labeled or described it as "Generic Cyclospasmol". These pharmacists derived no unfair profit to themselves and caused respondent no injury. The description which they used does not constitute trademark infringement since "Generic Cyclospasmol" is an accurate description of the

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constituted an identification of one source, since the same colors had been available for almost five years from many sources. *Cf.*, Comment, *Product Simulation in the Eighth Circuit*, 57 NEB.L.REV. 91, 139-140 (1978) (hereinafter *Product Simulation*). *See also Ives* II at Pet.App. 48a, n.14.

50. In view of this finding, the District Court did not reach the issue of whether there had been trademark infringement as such in the case of the instances of so-called mislabelling.

contents of the container. In view of the manner in which prescription pharmaceuticals are sold, there was no evidence of any actual or likelihood of confusion. Therefore, such use is not prohibited by the trademark laws.

B. The finding of contributory infringement was in any event erroneous. Such a finding under the applicable legal precedent laid down by the *Ives* II ruling required a showing that petitioner had implicitly suggested to druggists that they engage in an act of trademark infringement and that such acts were widespread. No such showing was made. The mere fact that petitioners used functional capsule colors similar to those of respondent is not a permissible basis for finding liability under Section 32 of the Lanham Act. The decision of the court below found the above-described requisite "suggestion" to druggists in "catalogs", most of which are not even distributed to druggists. The content of these catalogs cannot be reasonably read as suggesting any unlawful conduct. They contain standard trade information of relevance and lawful interest to the parties to whom they are directed. Basing a finding of liability on petitioner's dissemination of this truthful information amounts to an impermissible infringement on the First Amendment right to free speech.

II.

Even assuming that a technical finding of liability can be supported, the Court of Appeals' direction that an injunction be entered prohibiting petitioner from utilizing the capsule colors at issue was improper. The prior decisions of this Court have clearly enunciated a public policy in favor of lawful imitation precluding such an injunction. Moreover, since colors of the prescription pharmaceuticals at issue were found by the District Court to be functional, the decision of the Second Circuit has given respondent an unlawful monopolistic, anti-competitive advantage. In effect respondent's expired patent monopoly has been extended in a significant respect to the detriment of consumers who derive the benefit of lower cost, high quality generic drugs. The Court of Appeals simply declined to adhere to this Court's earlier decisions, which hold that other prophylactic measures, but not a ban on utilization of color, could be applied. The continued force of such earlier rulings should be reaffirmed.

ARGUMENT

I. THE TRUTHFUL COMPARATIVE USE OF A TRADEMARK IN LABELING AND ADVERTISING FORMS NO LEGAL BASIS FOR A FINDING OF TRADEMARK INFRINGEMENT OR CONTRIBUTORY TRADEMARK INFRINGEMENT

Petitioner Inwood respectfully submits that the *Ives* IV holding, which found petitioners liable for contributory trademark infringement under §32 of the Lanham Act should be reversed since neither trademark infringement nor contributory trademark infringement occurred under the applicable legal criteria.

A. THE IVES IV MAJORITY OPINION ERRED IN ASSUMING THAT PHARMACISTS HAD COMMITTED TRADEMARK INFRINGEMENT

It is axiomatic that Inwood and the other petitioners could not have been held liable for contributory trademark infringement unless the acts to which they supposedly contributed constituted trademark infringement in the first instance.[51] Yet, the *Ives* IV decision fails to deal with the threshold issue raised by petitioners below as to whether the supposed "additional evidence" of mislabeling established trademark infringement under the statutory criteria and applicable case law.

As noted by the District Court and Judge Mulligan in his dissent, the pharmacists in question had labeled or orally described the drug products at issue as a generic version of CYCLOSPASMOL [*Ives* II at Pet.App. 60a, 88a-89a].

The trademark laws do not grant a right "in gross" which is protectible against the whole world, in the abstract, without consideration of the facts and circumstances of each particular case. 1 Gilson, TRADEMARK PROTECTION AND PRACTICE, §5.09[3] at 5-76, 5-77 (1980). This basic tenet of

51. *Cf., Reid, Murdoch & Co. v. H.P. Coffee Co.*, 48 F.2d 817 (8th Cir.), *cert. denied*, 284 U.S. 621 (1931); *Stix Products, Inc. v. United Merchants & Mfrs., Inc.*, 295 F.Supp. 479 (S.D.N.Y.1968); *John B. Stetson Co. v. Stephen L. Stetson Co.*, 14 F.Supp. 74 (S.D.N.Y.), *modified*, 85 F.2d 586 (2d Cir.), *cert. denied*, 299 U.S. 605 (1936).

trademark law is central to the Lanham Act's definition of what constitutes trademark infringement:

> "(1) Any person who shall, without the consent of the registrant (a) use in commerce any reproduction . . . of a registered mark. . .*which such use is likely to cause confusion, or to cause mistake, or to deceive;* . . .shall be liable in a civil action for the remedies hereinafter provided." [15 U.S.C. §1114(1)(a)] [emphasis added][52]

While the commentators have identified a split among the Circuits, as yet unaddressed by this Court, as to whether the requisite test of likelihood of confusion, mistake or deceit is one of fact, law or a mixed question of law or fact, *see* J.T. McCarthy, TRADEMARKS AND UNFAIR COMPETITION §23:22 (1973) ("McCARTHY"), there is no dispute that the finding must be made. *Id.*, and cases cited at §23:1 n.1. In this case no such finding was made.

Never before has any court held that the mere description of one product as a generic equivalent of a trademark product is sufficient to constitute trademark infringement under the Lanham Act. To state, as occurred here, that a product is "Generic Cyclospasmol" clearly indicates that it is not the trademarked product but rather a generic version thereof. There was no evidence that patients receiving such a drug product pursuant to a lawful substitution were in any way confused or deceived. Nor has there been any judicial finding of even a likelihood of confusion. Indeed the absence of evidence of actual confusion in cases of lawful substitution after more than five years of marketing by petitioners raises a strong presumption that there is little likelihood of confusion. *See Pignons S.A. De Mecanique De Precision* v. *Polaroid Corp.*, 657 F.2d 482, 490-91 (1st Cir. 1981); *Amstar Corp.* v. *Domino's Pizza, Inc.*, 615 F.2d 252, 263 (5th Cir.), *cert. denied*, 449 U.S. 899 (1980).

That a comparative identification of one product by reference to another's trademark does not give rise to liability was established by this Court in the landmark case of *Saxlehner* v. *Wagner*, 216 U.S. 375 (1910), where Justice Holmes recognized that:

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52. The same criteria are also found in §32(1)(b) of the Act [15 U.S.C. §1114(1)(b)].

> "[t]he real intent of the plaintiff's bill, it seems, is to extend the monopoly of her type of bitter water, by preventing manufacturers from telling the public in a way that will be understood what they are copying and trying to sell. But the plaintiff has no patent for the water, and the defendants have a right to reproduce it as nearly as they can. They have a right to tell the public what they are doing and to get whatever share they can in the popularity of the water by advertising that they are trying to make the same article and think that they succeed . . .By doing so they are not trying to get the good will of the name, but the good will of the goods." *Id.* at 380.

The clear precedent prior to *Ives* IV established that the use of such written and oral terms[53] "generic Cyclospasmol" or "same as Cyclospasmol" or "equivalent to Cyclospasmol" by the pharmacist did not constitute an infringement of the CYCLOSPASMOL trademark. *See Champion Spark Plug Co.* v. *Sanders,* 331 U.S. 125, 128 (1947); *Prestonettes, Inc.* v. *Coty,* 264 U.S. 359, 368-369 (1924); *Societe Comptoir de L'Indus., etc.* v. *Alexander's Dept. Stores,* 299 F.2d 33, 36 (2d Cir. 1962); *Taylor Instrument Companies* v. *Fawley-Brost Co.,* 139 F.2d 98, 102-103 (7th Cir. 1943), *cert. denied,* 321 U.S. 785 (1944); *Electric Auto-Lite Co.* v. *P&D Mfg. Co.,* 78 F.2d 700, 702-703 (2d Cir.), *cert. denied,* 296 U.S. 648 (1935); *Geisel* v. *Poynter Products,* 295 F.Supp. 331, 352-354 (S.D.N.Y. 1968).[54]

Consideration of the question of trademark infringement in the context of a product dispensed by a pharmacist for a patient begins with a recognition that the patient does not purchase a prescription drug product by unilaterally selecting the drug product of his or her choice. As found by the district court, patients do not perceive the significance of a trademark as identifying source for prescription drugs, since brand-name promotion is limited exclusively to professionals:

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53. Oral explanations are clearly sufficient and in fact have sometimes been required to avoid liability for trademark infringement. *See, e.g., Coca-Cola Co. v. Dorris,* 311 F.Supp. 287 (E.D.Ark. 1970).

54. *See also Smith v. Chanel, Inc.,* 402 F.2d 562, 564 (9th Cir. 1968); *Viavi Co. v. Vimedia Co.,* 245 F. 289, 292 (8th Cir. 1917), *cert. denied,* 246 U.S. 664 (1918); McCARTHY at §25.14 at 192.

> "Ives argues that because 'Cyclospasmol' is a trademark which only it can use, a patient who identifies a cyclandelate capsule as 'Cyclospasmol' is necessarily indicating that he believes the drug comes from a single source. But even as to the trademark itself we must 'remember that relief always depends upon the idea that no man shall be allowed to mislead people into supposing that his goods are the plaintiff's, and that there can be no right or remedy until plaintiff can show that at least presumptively this will result.' *Bayer Co.* v. *United Drug Co.*, 272 F. 505, 509-510 (S.D.N.Y. 1921) (L.Hand, J.)"
>
> "No doubt to physicians and pharmacists the word 'Cyclospasmol' signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaign, and they play no role in choosing what drug to buy. Nothing in the record suggests that they 'understand by the word anything more than a kind of drug to which for one reason or another they [have] become habituated.' *Id.* at 510. Such patients as read their prescriptions do not attribute to Cyclospasmol 'any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic value.' *Id.*" *Ives* III at Pet.App. 66a-67a.

See Bayer Co. v. *United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921); *Syntex Laboratories, Inc.* v. *Norwich Pharmacal Co.*, 315 F.Supp. 45, 49 (S.D.N.Y. 1970)[55], *aff'd*, 437 F.2d 566 (2d Cir. 1971). As noted by Professor McCarthy:

> "Some products, such as prescription drugs, may be sold only to or through a professional class of

55. In *Syntex*, Judge Mansfield noted that, "[e]xcept for the remote possibility of confusion on the part of a patient who has a quantity of both products, prescribing physicians and dispensing pharmacists constitute the class within which confusion between plaintiff's and defendant's products is of concern to us." *Id.* at 49. *Cf., Pfizer & Co. v. Generic Formulae, Inc.*, 275 F.Supp. 421, 423 (E.D.N.Y. 1967). *See also* A. Seidel, S. Dubroff, and E. Gonda, TRADEMARK LAW AND PRACTICE ¶16.08 at 424 (1963); CALLMAN §83.1(m) at 195 (Supp. 1980).

> customers. Such professionals may be trained to recognize long and complicated terms as the generic name of a product, whereas the ordinary customer would unconsciously reject a complicated term and long for some short, easy to remember generic name. For example, medical doctors are familiar with the long, tongue-twisting generic terms such as dextro-amphetamine sulfate, or oxytetracycline. But the consumer may reject such terms and seize upon what the seller considers a trade mark—such as Dexedrine or Terramycin. The consumer may consider such short terms as the generic 'name' of the drug, whereas doctors are trained to know that Dexedrine and Terramycin are merely brand names—legal trademarks of only one producer of the drug." McCARTHY at §12.2B at 407.[56]

In arguing that the acts of the pharmacists constituted trademark infringement, Ives was in effect claiming that their trademark functions as such to patients as a class—contrary to historical experience in the industry. It was therefore error for the Second Circuit to assume *sub silentio* that any appearance of the word "CYCLOSPASMOL" on the label of a dispensing container *per se* produced patient confusion.

The "additional evidence" demonstrated not only an absence of actual confusion, but in fact the "unlikelihood" of confusion: (1) The prescription presented to the pharmacists expressly affirmed that substitution was permissible; (2) almost all of the pharmacists did not use the word "CYCLOSPASMOL' alone, but explained, either orally or in writing, that a generic product was being dispensed; (3) each patient received the drug authorized by the physician and the New York drug substitution law; (4) all but one pharmacist charged an appropriately reduced generic price; and (5) Ives suffered no competitive injury from the sales. To classify these instances as trademark infringement is to exalt form over substance.[57]

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56. *See also* Tr. 226-227, J.A. 161a; Premo Ex. 63 at 58-59, Tr. 760, J.A. 461a. *Cf., DuPont Cellophane Co. v. Waxed Products Co.*, 85 F.2d 75, 84 (2d Cir.), *cert. denied*, 299 U.S. 601 (1936).

57. In the context of lawful substitution, an interesting jurisdictional question is raised concerning the interstate commerce requirement of §32(1)(a) of the Lanham Act. *See* Annotation, 15 ALR Fed 368 (1973).

It appears that the *Ives* IV majority was oblivious to the distinction under the trademark law between utilizing a trademark as a deceptive and misleading source of origin and the innocent use by the pharmacist, as shown by the survey which comprised the "additional evidence" introduced by Ives.[58]

It is important to emphasize that the action of these pharmacists were not characterized as "mislabeling" because they falsely identified the product as "Generic Cyclospasmol". To the contrary, this term accurately described the product. The pharmacists' "offense" was that they varied from the technical labeling requirements of the New York drug substitution law in not listing the unfamiliar generic name and/or the name of the generic manufacturer [Tr. 813-814, J.A. 270a]. Having charged the generic price, the pharmacists could not have made such omissions for any ulterior or unlawful motive [Tr. 820, J.A. 273a]. Ives suffered no loss of sales from the action of the pharmacist in filling the prescription correctly.

Ives IV has thus erroneously transformed a technical violation of the New York drug labeling law into a finding of *per se* trademark infringement. Under applicable trademark principles, infringement simply did not occur. Infringement can only be of the public's right to be free of confusion and the markholder's right to be free of unfair competition—neither was shown to have occurred here. Infringement does not exist, even though the marks are identical and the goods very similar, where the evidence indicates no likelihood of confusion. *See Application of E.I.DuPont & De Nemours & Co.*, 476 F.2d 1357 (CCPA 1973). It is respectfully submitted that the Court of Appeals' finding of infringement is erroneous and must be reversed.

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58. For example, the opinion states that 2 out of 25 pharmacists in a survey conducted by Premo, demonstrating a complete absence of illegal substitution, had nevertheless labeled the generic cyclandelate as CYCLOSPASMOL [*Ives* IV at Pet.App. 81a-82a, n.7]. However, a stipulation entered into in the District Court expressly states that the two vials in question were labeled "Cyclospasmol Generic," and the pharmacists charged the appropriately lower generic price [Pl.Ex. 142, Tr. 726-731, J.A. 375a-382a].

B. THE IVES IV OPINION ERRONEOUSLY APPLIED THE DOCTRINE OF CONTRIBUTORY TRADEMARK INFRINGEMENT AND IN SO DOING INTERFERED WITH PETITIONERS' EXERCISE OF THEIR FIRST AMENDMENT RIGHT TO FREE SPEECH

The Second Circuit's finding that petitioners implictly suggested that pharmacists engage in trademark infringement is erroneous and stretches the doctrine of contributory trademark infringement to a point where it threatens competition in the field of prescription drugs.

The Lanham Act makes express provision in §32 for primary trademark infringement. It also makes an express provision for a type of contributory trademark infringement not at issue here, *i.e.*, where a party affixes an infringing mark to goods which are intended for subsequent infringing use in interstate commerce [15 U.S.C. §1114(1)(b)]. However, the statute makes no express provision for the species of contributory trademark infringement at issue in this case. *See* Cooper, *Trademark Aspects of Pharmaceutical Product Design*, 70 TMR 1, 39-40 (1980).

It is well-established that liability for contributory trademark infringement may nevertheless be extended beyond those who affix the infringing mark or sell goods with such a mark. Persons who knowingly cooperate in illegal and tortious activity by encouraging others to engage in trademark infringement have been found liable. This category of contributory trademark infringement has historically developed as a matter of common law outside the direct provisions of the Lanham Act.[59] Prior to the decision of Judge Mansfield below, no court had ever held that this type of contributory trademark

59. *See, e.g., Stetson*, 85 F.2d at 588; *Andrew Jurgens Co. v. Bonded Products Corp.*, 21 F.2d 419, 424 (2d Cir. 1927), *cert. denied*, 275 U.S. 572 (1928); *Cuervo v. Jacob Henkell Co.*, 50 F. 471 (S.D.N.Y. 1892). *See also Corning Glass Works v. Jeanette Glass Co.*, 308 F.Supp. 1321 (S.D.N.Y.), *aff'd per curiam*, 432 F.2d 784 (2d Cir. 1970). *But see* Judge (later Justice) Minton's holding in *Zangerle & Peterson Co. v. Venice Furniture Novelty Mfg. Co.*, 133 F.2d 266 (7th Cir. 1943).

infringement was actionable directly under §32 of the Lanham Act.[60]

Whether or not Judge Mansfield was correct in reading the doctrine of contributory trademark infringement directly into §32 of the Lanham Act, the criteria established by Judge Friendly in *Ives* II were the guidelines and framework within which the case was tried by the District Court, and pursuant to which Judge Mansfield applied and conducted appellate review. The two-prong standard articulated in *Ives* II was as follows:

> "The authorities later reviewed indicate to us that a manufacturer or wholesaler would be liable under Section 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described. The proper criteria are stated in *Coca-Cola Co.* v. *Snow Crest Beverages, . . .*" *Ives* II at Pet.App. 35a.

No claim was ever made that any of the petitioners had *continued* to sell capsules to a druggist after learning or knowing that the druggist was actually engaging in trademark infringement. *Ives* III at Pet.App. 59a, *Ives* IV at Pet.App. 87a (Mulligan, J.). The sole issue, therefore, was whether petitioners had suggested, even if only by implication, that druggists engage in such conduct.

Under this prong, mere imitation of color configuration without more is not sufficient to establish liability. *See William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526, 531 (1924); *Nugrape Co. of America* v. *Glazier*, 22 F.2d 596, 597 (5th Cir. 1927); *Smith, Kline & French Laboratories* v. *Waldman*, 69 F.Supp. 646, 648 (E.D.Pa. 1946); *Coca-Cola Co.* v. *Snow Crest*

60. *Ives* II, for example, refers to the leading decision of *Coca-Cola Co. v. Snow Crest Beverages*, 64 F.Supp. 980 (D.Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947). In that case, contributory infringement was clearly raised as a matter of common law rights, rather than as a federal cause of action under §32. *Cf., Stix Products, Inc. v. United Merchants & Mfrs., Inc., supra.*

Beverages, 64 F.Supp. at 990.[61] For a finding of liability, there must be some actual suggestion, express or implied, that the infringer engage in the unlawful conduct.[62] *See, e.g., Smith, Kline & French Laboratories* v. *Clark & Clark*, 157 F.2d 725 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946).

Applying this standard, Judge Friendly in *Ives* II found:

> "[T]he court was justified in concluding that Ives failed to adduce the quantum of proof necessary to require issuance of a temporary injunction for contributory infringement even on what we deem the proper standard of liability under §32. Ives' proof was limited to 15 instances of improper substitution and defendants conceded only that the identity of color made this easier if a druggist were so inclined." *Ives* II at Pet.App. 35a-36a.
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> * * *
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> "As noted above, the evidence of improper substitution was limited to 15 prescriptions. Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Id.* at Pet.App. 53a.

At trial, Ives abandoned all efforts to show that "illegal substitution" of cyclandelate[63] was more widespread than the

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61. *See also Swank, Inc. v. Anson, Inc.*, 196 F.2d 330 (1st Cir. 1952); *Zangerle & Peterson Co. v. Venice Furniture Novelty Mfg.Co., supra; Famolare, Inc. v. Melville Corp.*, 472 F.Supp. 738 (D.Haw. 1979), *aff'd without opinion*, 652 F.2d 62 (9th Cir. 1981); *Pezon et Michel v. Ernest R. Hewin Associates, Inc.*, 270 F.Supp. 423 (S.D.N.Y. 1967); *Mattel, Inc. v. Goldberger Doll Mfg. Co., Inc.*, 200 F.Supp. 517 (E.D.N.Y. 1961). *Cf., Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964); and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

62. Ives had argued in the appeal of *Ives* I that mere copying of color was sufficient to establish liability under §32, as well as secondary meaning under §43(a). This was rejected. *Ives* II at Pet.App. 50a-51a.

63. *i.e.*, a prescription which by law may be filled only with the specific brand product is filled instead with a different product. *See* Pet.App. at 112a-120a.

original evidence submitted. *Ives* III Pet. at App. 59a.[64] A survey to determine the extent (if any) of illegal substitution of cyclandelate could easily have been done [Tr. 120a, J.A. 106a-107a; Tr. 568, J.A. 204a], but the record shows that Ives deliberately chose not to do so [Tr. 86, J.A. 145a].[65] Instead, Ives attempted to show that in cases of *lawful* substitution, the word Cyclospasmol was sometimes applied to the dispensing container. Ives thus sought to satisfy Judge Friendly's requirement that the trademark infringement be "much more widespread" solely with reference to lawful substitution, and conducted its survey attempting to provide such "additional evidence" as previously described.

In *Ives* IV, Judge Mansfield accepted Ives' claim that the "additional evidence"—described as evidence of "mislabeling"—was sufficient and that petitioners could thereby be found liable for having implicitly suggested that pharmacists engage in such "mislabeling". According to the majority opinion, the criteria laid down in *Ives* II were satisfied as follows:

> "The additional evidence introduced by Ives at trial was clearly sufficient to establish a §32 violation. By using capsules of identical color,

64. At trial, the following colloquy took place:

> "THE COURT: I take it that you are not — I think I may have asked you this — you are not going to offer any testimony of shopping that shows an illegal substitution."
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> "MS. DRISCOLL: Not other than those we had on the initial motion." Tr.394. [*See also* Tr. 86, J.A. 145a].

65. The evidence of illegal substitution was thus confined to a total of either four, or at most nine, pharmacies. *See* n.25 *supra*, and accompanying text. In confusing dicta, Judge Mansfield nevertheless describes "illegal substitution" as widespread. At the request of Ives, judicial notice was taken of six indictments of pharmacies, which were handed down after the trial was completed. *Ives* IV at Pet.App. 84, n.5. These pharmacies were alleged to have illegally substituted cyclandelate. If judicial notice was intended as a means of filling a huge gap in the evidence below, it was clearly improper. *See Goland v. CIA*, 607 F.2d 339, 371-372 (D.C.Cir. 1978), *cert. denied*, 445 U.S. 927 (1980); F.R.Civ.P. 60(b). *Cf., United States v. Lowell*, 649 F.2d 950 (3d Cir. 1981). We cannot believe, however, that Judge Mansfield seriously intended that by raising the total number of pharmacists to fifteen, at most, that illegal substitution of cyclandelate could be characterized as "widespread". There are more than 140,000 pharmacists in the United States. *See* 20 APhARMACY WEEKLY at 170 (November 4, 1981). *See also Ives* IV at Pet.App. 90a (Mulligan, J.).

> size and shape, together with a catalog describing their appearance and listing comparative prices of CYCLOSPASMOL and generic cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL[66] or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage. This amounted to a suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct." *Ives* IV at Pet.App. 82a.

No such implicit suggestion can be found in the so-called catalogs. As regards Inwood, the statement that its price sheet amounted to a suggestion by implication that *druggists* take advantage of an opportunity to engage in misconduct defies rational analysis. Even assuming that this price sheet would have been seen by some druggists, the mere advertising of the availability of products for sale, a listing of the product to which they were generically equivalent and a description of the appearance of all products could hardly amount to an "implication" to druggists that they engage in misconduct. On the contrary, it simply was a notification that the product was available for sale at the prices stated. The manufacturers'

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66. This is the first of various instances where Judge Mansfield comingles the concept of "illegal substitution" with that of technical "mislabelling". The additional evidence referred to in this paragraph of the opinion and described earlier by Judge Mansfield dealt only with *mislabeling* and not illegal substitution. There are other troublesome factual errors in the opinion. As part of the "additional evidence", Judge Mansfield refers to "9 out of 17 instances" of alleged mislabeling. We are unable to find any testimony in the Record identifying the seventeen instances of which these nine are said to be a part. Significantly, no such reference is found in Judge Nickerson's opinion. The *Ives* IV opinion also states that many generic drugs are successfully marketed in capsules or tablets that do not copy Ives' product. The court lists one example. *See Ives* IV at Pet.App. 85a. The actual evidence, was that the relied-upon example was the only such product [Tr. 20]. There were no others and, as discussed, one company which had tried to market in a different color was forced to discontinue it because the unfamiliar color was not acceptable to its hospital customers. Another error with respect to the characterization of the testimony of an *Ives* witness, Lawlor, as a "witness called by appellees" was corrected. *See Ives* IV at Pet.App. 85a, 93a. After the correction, the statement loses its force.

catalogs did not, as Judge Mansfield suggests, list comparative prices of CYCLOSPASMOL and generic cyclandelate. Some of the wholesaler catalogs did so simply because these companies offered both products for sale. Moreover, as noted by Judge Mulligan:

> "[I]t was common in the industry to list the generic drug next to the brand name drug . . . Thus, it would seem that juxtaposition of the generic and brand-name drug would be imperative for generic manufacturers to compete effectively." *Ives* IV at Pet.App. 90a, n.4. *See also* Tr. 657-659, J.A. 225a-227a.

The most that Judge Mansfield could state in describing petitioners' price sheets was that they were "pro-substitution" catalogs. *Ives* IV at Pet.App. 76a. Assuming *arguendo* that this description is accurate, it highlights the error made in the court below. In some of the early cases, companies dealing directly with pharmacies were found to have advertised one or two products in their literature which emphasized similarity of color *(e.g.,* "Color Guaranteed") and differences in price where the brand-name product was not offered for sale by the company.[67] Additional illicit suggestions such as "keep the substitution cards out of sight" were also found.[68] These cases occurred at a time when substitution was unlawful in almost all states and generic prescribing was extremely limited [Tr. 765-766, J.A. 263a]. Under those circumstances, a finding that an isolated company's action was "pro-substitution" might fairly be construed as an implied suggestion to unlawfully substitute. Today, as previously noted, the situation is far different. Even if petitioners' catalogs are "pro-substitution", that can be no basis for an implication that unlawful criminal activity is suggested thereby.[69]

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67. *See, e.g., Ross-Whitney Corp. v. Smith, Kline & French Laboratories,* 207 F.2d 190 (9th Cir. 1953); *Smith, Kline & French Laboratories v. Broder,* 125 U.S.P.Q. 299 (S.D.Tex. 1959); *Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp.,* 90 F.Supp. 976 (S.D.N.Y. 1950); *Martin H. Smith Co. v. American Pharmaceutical Co.,* 270 N.Y. 184 (1936).

68. *See Upjohn Co. v. Schwartz,* 246 F.2d 254, 260-61 (2d Cir. 1957).

69. Contrary to the statements in the *Ives* IV opinion, the instances of mislabeling did not constitute any economic advantage to the druggists or petitioners.

Instructive in this regard is Judge Wyzanski's decision in *Coca-Cola Co.* v. *Snow Crest Beverages, supra,* which describes a situation somewhat comparable to the case at bar. The Coca-Cola Company there attempted to hold a competitor liable as a contributory trademark infringer because patrons of certain bars, upon requesting a drink consisting of or supposedly including Coca-Cola, were in fact receiving a substitute cola marketed by the defendant. Presumably the substitution might not have occurred if the colors of the colas had been different.[70] In *Snow-Crest,* as Ives does here, Coca-Cola argued that it was not seeking to prohibit competition from another cola drink, but merely to hold the competitor liable for the acts of bartenders in unlawfully substituting the competitive cola to the ultimate customer. In what has become the classic and definitive answer to Ives' argument, Judge Wyzanski held:

> "But in the case at bar plaintiff seems to urge that defendant's obligation goes further. Plaintiff appears to contend that once a defendant has knowledge that some customers of bars specifically order 'rum (or whiskey) and Coca-Cola' and that there are in all probability some rogues in the bar business as in other businesses, the defendant has a duty either (a) not to sell to any bar a cola until defendant first creates for that cola special consumer demand, or (b) at least not sell a cola to a bar before defendant has particularly cautioned the bar to be scrupulous against substitution. The law does not go that far." 64 F.Supp. at 989.

The record here shows far *fewer* instances of illegal substitution of cyclandelate than those which were present in *Snow Crest. See Id.* at 986-987. The admitted fact that some unscrupulous pharmacists will engage in illegal substitution should not be a basis for imposing contributory liability on

70. Coca-Cola for many years had attempted without success to compel other companies to use a different coloring for the cola drinks. Almost uniformly, the courts, including this Court, held that the public, having become accustomed to the color of cola as found in the Coca-Cola beverage, could not be deprived of the familiar color when the same product was sold by a competitor. *See Coca-Cola Co. v. The Koke Company of America,* 254 U.S. 143 (1920). *See also* Note, *Unfair Competition and the Doctrine of Functionality,* 64 COLUM. L REV. 544, 558, n.94 (1964) (hereinafter "Functionality").

Inwood or the other petitioners[71]. That others in a minority of instances will label lawfully dispensed generic products as Cyclospasmol without any ill motive or prejudice to Ives should not support a hindsight conclusion that this inadvertent conduct was implicitly suggested by petitioners in price sheets and catalogs. *Cf. Fortnightly Corp.* v. *United Artists Television, Inc.*, 392 U.S. 390, 397 (1968).[72]

A very serious constitutional issue is also raised by the Second Circuit's attempt to utilize the exercise of petitioners' commercial free speech rights as a basis for subjecting them to liability for contributory infringement. This Court has noted that constitutional free speech protections apply to pharmacists when they convey price information to consumers.[73] *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). *See also Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977). The same right applies to petitioners' attempts to market a product in competition with that of Ives. Significantly, cyclandelate is a drug for which

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71. *See Famolare, Inc. v. Melville Corp.*, 472 F.Supp. at 74/. *See also* McCARTHY,§25.2 at 175 (doctrine of contributory infringement does not demand that defendants refuse to sell to dealers who merely might pass-off its goods).

72. The doctrine of contributory trademark infringement first originated as a derivative of the same doctrine in the field of patents. *Howard Dustless Duster Co. v. Carleton*, 219 F. 913, 915 (D.Conn. 1915). Under the patent law, it is an absolute defense to a charge of contributory patent infringement if the contributorily infringing item is a staple item of commerce having a substantial non-infringing use. 35 U.S.C. §271(b). *See also Henry v. A.B. Dick Co.*, 224 U.S. 1, 48 (1912). To hold otherwise, this Court has observed, would "block the wheels of commerce." *Id.* There can be no doubt of the substantial non-infringing use of petitioners' products in the marketplace. In fact, the primary and overwhelming majority use of petitioners' products is by pharmacists who commit no act of which Ives can complain. *See* Callman's discussion of the substantial non-infringing use doctrine in the context of trademarks. CALLMAN, §82.1(m) at 203-206 (Supp. 1980). *See also* discussion in *Universal City Studios, Inc. v. Sony Corp. of America*, 659 F.2d 963 (9th Cir. 1981). It surely cannot be the law that under the doctrine of contributory trademark infringement, Ives is entitled to an even greater degree of protection after its patent has expired.

73. In the context of prescription pharmaceuticals, the capsule colors themselves emerge as a form of speech. *See* discussion, *supra*. Petitioners cannot constitutionally be compelled by way of capsule color to make a negative and inaccurate statement about their own product. Their free speech rights should further protect the truthful statement which identity of color implies, *i.e.*, that petitioners' products are not therapeutically different from those previously taken by the patient.

substitution is permissive rather than mandatory. Petitioners' price sheets and catalogs indicate the truthful information that their products are generic versions of the brand-name product and thereby eligible for permissive substitution.

In recognition of this Court's affirmation of the right to commercial free speech, lower courts have recognized that the Lanham Act should not be construed in a manner that would bring it into conflict with First Amendment interests. *See Stop the Olympic Prison* v. *U.S. Olympic Committee,* 489 F.Supp. 1112, 1124 (S.D.N.Y. 1980). *See also Triangle Publications, Inc.* v. *Knight-Ridder Newspapers, Inc.,* 445 F.Supp. 875, 884 (S.D. Fla. 1978), *aff'd on other grounds,* 626 F.2d 1171 (5th Cir. 1980) (court observed that comparative advertising which uses another's trade name "is in harmony with the fundamental objectives of free speech and free enterprise in a free society."); *Fur Information and Fashion Council, Inc.* v. *E.F. Timme & Son, Inc.,* 364 F.Supp. 16, 22 (S.D.N.Y. 1973), *aff'd on other grounds,* 501 F.2d 1048 (2d Cir.), *cert. denied,* 419 U.S. 1022 (1974).[74]

The Second Circuit's holding has placed generic drug companies on the horns of a dilemma. If they choose to engage in the standard forms of advertising long prevalent in the industry, they now run the risk that, under the Second Circuit opinion, they may be automatically liable for contributory trademark infringement and thereby lose the right to market an important functional and competitive feature of their product.[75] If they choose not to advertise under this threat of liability, then, as against them, the competitor's trademark (as Justice Holmes observed) has been impermissibly extended to the product itself. *See Saxlehner* v. *Wagner,* 216 U.S. at 380. First Amendment rights should not be so cavalierly restricted by the expansive approach to contributory trademark infringement taken by the

74. *Cf., Rosemont Enterprises, Inc. v. Random House, Inc.,* 366 F.2d 303, 311 (2d Cir. 1966) (Lumbard, J., concurring), *cert. denied,* 385 U.S. 1009 (1967); *Time, Inc. v. Bernard Geis Associates,* 293 F. Supp. 130, 145 (S.D.N.Y. 1968).

75. The extensive evidence of functionality discussed *supra* rebuts any supposed inference that petitioners intended the identity of capsule color as "an implied suggestion." *See Famolare, Inc. v. Melville Corp., supra.* Whether or not Judge Mansfield was convinced on the question of functionality cannot belie the fact that identical colors were used consistent with the long-standing industry practice.

lower court. It is respectfully submitted that the finding of contributory trademark infringement is thus factually erroneous, legally unsound, and constitutionally impermissible.

II. SECTION 32 OF THE LANHAM ACT MAY NOT GRANT A TRADEMARK OWNER MONOPOLY RIGHTS IN THE COLOR OF ITS PRODUCT

Although the holding of *Ives* IV is caught up in the complexities of trademark infringement and contributory trademark infringement, the end result is remarkably clear. The court held that as a remedy for the supposed violation of law, Ives must be granted a perpetual monopoly on the colors blue and blue/red for cyclandelate and an injunction to that effect was promptly entered by the District Court. *See Ives* V at Pet.App. 96a, 98a. Judge Mansfield explained that such an injunction would be the "simplest way" to grant plaintiff relief. *Ives* IV at Pet.App. 86a.

In other contexts, simplicity undoubtedly has its virtue. Here, the sought-after simplicity directly contravenes almost 100 years of controlling precedent. *See Coats* v. *Merrick Thread Co.*, 149 U.S. 562, 573-574 (1893); *A. Leschen & Sons Rope Co.* v. *Broderick & Bascom Rope Co.*, 201 U.S. 166, 171 (1906); *Schlitz Brewing Co.* v. *Houston Ice Co.*, 250 U.S. 28, 29-30 (1919); *Coca-Cola* v. *The Koke Company of America*, 254 U.S. at 147; *William R. Warner* v. *Eli Lilly & Co.*, 265 U.S. at 531; *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 121-123 (1938); *Sears*, 376 U.S. at 230-233; *Compco*, 376 U.S. at 239.[76]

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76. *Accord, Diamond Match Co. v. Saginaw Match Co.*, 142 F. 727, 729 (6th Cir. 1906), *cert. denied*, 213 U.S. 598 (1908); *Newcomer & Lewis v. J.A. Scriven Co.*, 168 F. 621 (6th Cir.), *cert. denied*, 214 U.S. 518 (1909); *Rice-Stix Dry Goods Co. v. J.A. Scriven Co.*, 165 F. 621 (6th Cir. 1908), *cert. denied*, 223 U.S. 708 (1911); *L.E. Waterman Co.*, 34 App.D.C. 185 (D.C.Cir. 1909); *Samson Cordage Works v. Puritan Cordage Mills*, 211 F. 603 (6th Cir. 1914); *Viavi Co. v. Vimedia Co.*, 245 F. 289 (8th Cir. 1917), *cert. denied*, 246 U.S. 664 (1918); *Zangerle & Peterson Co.*, 133 F.2d at 270; *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F.2d at 731; *Campbell Soup Co. v. Armour & Co.*, 175 F.2d 795, 798-799 (3d Cir.), *cert. denied*, 338 U.S. 847 (1949); *Tast-T-Nut Co. v. Variety Nut & Date Co.*, 245 F.2d 3, 6-7 (6th Cir. 1957); *Upjohn Co. v. Schwartz*, 246 F.2d at 256; *Norwich Pharmacal Co. v. Sterling Drug Inc.*, 271 F.2d at 572-573; *Unistrut Corp. v. Power*, 280 F.2d 18, 23-24 (1st Cir. 1960); *Plastilite Corp. v. Kassnar Imports*, 508 F.2d 824 (CCPA 1975). *Cf., Keene Corp. v. Paraflex Industries, Inc.*, 653 F.2d 822, 827-828 (3d Cir. 1981); *International Order of Job's Daughters v. Lindeburg & Co.*, 633 F.2d 912 (9th Cir. 1980), *cert. denied*, ____ U.S. ____, 69 L.Ed.2d 956 (1981).

The central principle of the foregoing cases is that free and open competition necessarily requires that "imitation" be encouraged and that the right to imitate, absent legitimate patent, trademark or copyright protection, cannot be constricted:

> "Sharing in the goodwill of an article unprotected by patent or trademark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested." *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. at 122.

See also American Safety Table Co. v. *Schreiber*, 269 F.2d 255, 272 (2d Cir.), *cert. denied*, 361 U.S. 915 (1959); Stern & Hoffman, *Public Injury and the Public Interest: Secondary Meaning in the Law of Unfair Competition*, 110 U.PA.L.REV. 935, 942 (1962); *Product Simulation*, 57 NEB. L.REV. at 91-92.

A competing philosophy has emerged which expounds the exact opposite of the principles noted above. Articulated most forcefully in a string of decisions rendered in the United States District Court for the District of New Jersey, this view asserts that there is a duty upon "second comers" to make their product appear as "different as possible" from that of that of their competitors.[77] The "simplicity" preference ennunciated in *Ives* IV accepts by implication the rationale (although not the legal holdings) of these cases.[78]

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77. *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980) *aff'g*, 481 F.Supp. 1184 (D.N.J. 1979); *Biocraft Laboratories, Inc. v. Merck & Co., Inc.*, ___ F.Supp. ___, Civ. Action No. 77-693 (D.N.J. Oct. 2, 1980); *Boeringer-Ingelheim GmbH v. Pharmadyne Laboratories*, 211 U.S.P.Q. 1163 (D.N.J. 1980); *Hoffman-La Roche v. Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980); *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., supra. See also Johnson & Johnson v. Quality Pure Mfg. Co.*, 484 F. Supp. 975, 982 (D.N.J. 1979).

78. The cases cited above have reached their result upon alleged violations of §43(a) of the Lanham Act [15 U.S.C. §1125(a)] and an expansive view of the concept of secondary meaning and the scope of the New Jersey state law of unfair competition. These legal issues are not before this Court.

The far-reaching consequences of the "different as possible" rule as a restraint on free competition are self-evident.[79] Some of the commentators have taken note of and seriously questioned the strength of the analysis which forms the basis of this protectionist trend. *See* Stern, *The Persantine, Librax & Elavil Decisions: Colourful Brands of Drugs*, 2 EUR. INTEL. PROP. REV. 59 (1981); CALLMAN at §82.1(m) at 195-206 (Supp. 1980).

The importance of the overall issue notwithstanding, the issues raised here relate to the following specific framework:

(1) The product at issue is a prescription drug for which patent protection has expired;

(2) During the life of the patent, patients receiving cyclandelate inevitably become accustomed to the color configuration used by Ives by virtue of its exclusive monopoly;

(3) Irrespective of patent (*e.g.*, the blue/red 400-mg. capsule), patients become familiar with a particular color configuration by virtue of long-term therapy;

(4) No secondary meaning has been found for either color configuration;

(5) Should the law permit the generic competitor to sell the prescription drug in the color to which the patient has become accustomed or should the law require it to use a color which is as different as possible?

(6) Should the Court now abandon its historic rule that a prohibition on copying is not permissible absent express federal statutory protection?

Petitioner respectfully submits that this Court should reaffirm the traditional rule that, whatever the theory of liability,

79. For example, in a variant of the same theme, one district court has gone so far as to hold that an amusement center trading under the name "Jellibeans" has the right to prevent a competitor from opening a similar establishment using the name "Lollipops." *Jellibeans, Inc. v. Skating Clubs of Georgia, Inc.*, ___ F.Supp. ___ No. C-80-1689A (N.D.Ga. May 19, 1981), reported in 540 BNA Patent, Trademark & Copyright Journal, A-5 (August 6, 1981).

under these circumstances the utilization of similar capsule colors may not be enjoined. *William R. Warner* v. *Eli Lilly & Co., supra; Norwich Pharmacal Co.* v. *Sterling Drug, supra; Upjohn Co.* v. *Schwartz, supra; Smith, Kline & French Laboratories* v. *Clark & Clark, supra; Smith, Kline & French Laboratories* v. *Waldman, supra. Cf., Sears, supra,* and *Compco, supra.*

First, the lower courts have too quickly dismissed the problem inherent in any sanction for monopoly of color. It is true that it is easy enough for one company to distinguish its capsule colors from those of a single competitor, but what happens when each subsequent manufacturer must utilize different colors for each dosage strength and still be as different as possible from every other color configuration of every other company making the same drug product?

> "Thus, a producer might market a red-and-white capsule to indicate 5 mg. strength, a red-and-green capsule for 10 mg. dosage and a red-and-yellow capsule for a 25 mg. strength. . . . Consider the confusion if a rival produced a generic red and yellow for 5 mg., red and white for 10 mg., and red and green for 25 mg. content? Then multiply the confusion with the other generic producers who may use the constant color red but vary the other colors for the different dosages of their product." *See* CALLMAN, §82.1(m) at 196-197 (Supp. 1980).

Second, the evidence of functionality, as found by the District Court, should as a matter of law and public policy preclude any company from monopolizing the colors of a prescription drug. The prior cases have recognized that a public which becomes accustomed to a particular color configuration should be entitled to receive the same configuration from a competing company at least in the absence of secondary meaning. *Pagliero* v. *Wallace China Co.*, 198 F.2d at 343. *See also Keene* v. *Paraflex, supra; Bliss* v. *Gotham Industries, Inc.*, 316 F.2d 848, 855 (9th Cir. 1963); *Application of Deister Concentrator Co.*, 289 F.2d 496, 505 (CCPA 1961); *Norwich Pharmacal Co.* v. *Sterling Drug, Inc., supra; J.C. Penney Co.* v. *H.D. Lee Mercantile Co.* 120 F.2d 949, 954 (8th Cir. 1941);

RESTATEMENT OF TORTS, §742 (1938); *Functionality*, 64 COLUM. L.REV. at 558-563.

Functionality of capsule colors was demonstrated in that patients would be "put off" by different colors, lawful substitution would be impeded, therapeutic efficacy could be compromised in terms of the psychological placebo function, and emergency and dosage identification would be hindered. Due to these factors, the prior cases, even after a finding of liability, refused to grant monopoly color rights to brand-name manufacturers and limited relief to other appropriate and less drastic measures. *William R. Warner* v. *Eli Lilly & Co., supra; Upjohn Co.* v. *Schwartz, supra; Smith, Kline & French Laboratories* v. *Clark & Clark, supra.*[80] Petitioners do not contend that it would be absolutely impossible to sell these drugs in different capsule colors. Petitioners' grievance is that they should not in the first instance be burdened with the significant competitive disadvantage of marketing a product whose first reception in the hands of the ultimate consumer leads that consumer to the erroneous (if not anxiety-producing and irreversible) conclusion that a mistake has been made in filling the prescription.

The infringement of petitioners' rights is particularly severe where, as here, patient association of color with therapeutic effect is developed during the lifetime of a patent monopoly. Upon expiration of the patent, petitioners should be entitled to the full enjoyment of the product as it enters the public domain. Since capsule-color is rightly or wrongly regarded by consumers as being associated with therapeutic efficacy, the color here is not mere trade dress, but functions at least in the patient's mind as an integral part of the product itself. The prohibition on copying capsule colors thereby impermissibly extends a significant aspect of the former patent monopoly. *Kellogg Co.* v.

80. In *Ives* II, Judge Friendly suggested that this Court's approach in *Warner v. Lilly* and *Kellogg Co. v. National Biscuit Co.*, could be appropriate here. *Ives* II at Pet.App. 53a. For an example of supplemental labeling which could eliminate the so-called mislabeling problems, *see* Pl.Ex. 82S, J.A. 695a. Additionally, in *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F.Supp. at 422-423, the court granted preliminary injunctive relief, but refused to extend it across the board to prohibit sales to dispensing physicians. Here, a blanket injunction was authorized, prohibiting sale to even institutional accounts and federal and state governments, even though there can be no opportunity for illegal substitution or mislabeling.

National Biscuit Co., supra; Singer Mfg. Co. v. *June Mfg. Co.*, 163 U.S. 169, 185 (1896). *See also Zangerle*, 133 F.2d at 269. It is the exclusive patent monopoly which gives the brand-name company the opportunity to develop color as an associational factor in the minds of patients.

The essence of the error in the *Ives* IV opinion lies in its utilization of the trademark laws as a means toward the end of creating a new, absolute, and perpetual property right in capsule colors. *Ives* IV thus turns the law of trademarks on its head. When this Court in *Sears* and *Compco* referred to "federal statutory protection" as a permissible basis for prohibiting copying, it did not intend that §32 of the Lanham Act could be so broadly construed as to effectively make color an automatic property right incident to a registered trademark. The public policy factors identified in those decisions should apply with no less force to the interpretation of federal statutes than to a restriction on state laws of unfair competition. If state laws of unfair competition may not, under *Sears* and *Compco*, prohibit copying where the federal laws have spoken and declined to do so, then those decisions may not be bypassed by the expedient holding that the trademark laws can accomplish the very same result.[81]

In *Goldstein* v. *California*, 412 U.S. 546, 571 (1973); and *Kewanee Oil Corp.* v. *Bicron Corp.*, 416 U.S. 470, 479-480 (1974), the majority opinions emphasized that it was not the intention of this Court to abandon the underlying principles of *Sears* and *Compco*. *See also Ives* II at Pet.App. 43a-45a. Petitioner Inwood respectfully requests that unless *Sears* and *Compco* are now to become devoid of any meaning, the Court should definitively reconfirm their validity be reversing the ruling of the Second Circuit.

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81. In effect, *Ives* IV reads the state law doctrine of contributory trademark infringement into §32 as a means of escaping the strictures of *Sears* and *Compco*.

CONCLUSION

Petitioner Inwood respectfully submits that the judgment of the Court of Appeals for the Second Circuit be reversed, and that the judgment of the District Court in *Ives* III, dismissing the complaint, be reinstated.

Dated. New York, New York
November 27, 1981

Respectfully submitted,

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IN THE

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and
PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

BRIEF ON THE MERITS OF PETITIONER PREMO PHARMACEUTICAL LABORATORIES, INC.

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Questions Presented

I. Whether the sale of a product with an appearance that simulates the unpatented and uncopyrighted appearance, principally the surface coloration, of another manufacturer's product which is identified by a registered word trademark can be enjoined on the ground that such sale contributes to the infringement of said trademark by purchasers and thus violates Section 32 of the Lanham Act, 15 U.S.C. §1114.

II. Whether the sale of a product as described in Question I can be enjoined on the ground that such sale constitutes or contributes to passing off and hence false designations of origin in violation of Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a).

III. Whether the sale of a product as described in Question I can be enjoined where the appearance of the product which has been copied is the one to which consumers became accustomed during the period when that product was protected by a patent and hence no other manufacturer could sell such a product.

IV. Whether the sale of a product as described in Question I to licensed professionals (pharmacists) can be enjoined on the ground that a small number of those professionals utilize the product to commit acts which leave them liable to criminal and/or civil penalties, including loss of license, even though the seller of the product did not counsel, suggest or induce such acts.

Statement Pursuant to Supreme Court Rules 21 and 28.1

The other parties to the proceeding in the court whose judgment is sought to be reviewed were appellees Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.

The parent company of petitioner Inwood Laboratories, Inc. is Forest Laboratories, Inc. Petitioner Premo Pharmaceutical Laboratories, Inc. is affiliated with Federal Pharmacal Co.

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BRIEF ON THE MERITS OF PETITIONER PREMO PHARMACEUTICAL LABORATORIES, INC.

Opinions Below

The first opinion of the district court denying respondent's request for preliminary injunctive relief on its primary claims is officially reported at 455 F. Supp. 939 (E.D.N.Y. 1978) (Pet. App. 1a).[1] The Court of Appeals decision affirming the district court's denial of preliminary injunctive relief is officially reported at 601 F.2d 631 (2d Cir. 1979) (Pet. App. 28a).

1. Citations in the form "Pet. App. ——a" refer to pages in the Appendices to the Petition for Certiorari filed herein.

The opinion of the district court after trial, dismissing respondent's complaint, is officially reported at 488 F. Supp. 394 (E.D.N.Y. 1980) (Pet. App. 54a). The opinion of the Court of Appeals which is at issue herein, reversing the district court decision on the merits, is officially reported at 638 F.2d 538 (2d Cir. 1981) (Pet. App. 71a).

Jurisdiction

The judgment of the United States Court of Appeals for the Second Circuit, sought to be reviewed herein, was entered on January 8, 1981. Petitioners' subsequent request for a rehearing was denied on February 25, 1981 without opinion. The jurisdiction of this Court is invoked under 28 U.S.C. Section 1254(1).

Statutes and Administrative Rules Involved

The statutory provisions involved herein are Sections 32 and 43(a) of the Lanham Act, 15 U.S.C. §§1114 and 1125(a) (Pet. App. 107a-111a).

Statement of the Case

Petitioner Premo Pharmaceutical Laboratories, Inc. ("Premo") adopts and incorporates by reference herein the Statement of the Case set forth in the Brief on the Merits of Petitioner Inwood Laboratories, Inc.

Summary of the Argument

The relief granted by the Second Circuit under Section 32 of the Lanham Act against copying of the appearance of respondent's products directly conflicts with the policy

against free and unrestricted copying of the unpatented and uncopyrighted appearance of articles of manufacture enunciated by this Court in *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp.* v. *Day-Brite Lighting Co.*, 376 U.S. 234 (1964). Moreover, there is no previous case where a court enjoined the copying of such an unpatented and uncopyrighted appearance on the ground of contributory trademark infringement. Instead, where the courts have found that encouragement or inducement of such infringement has taken place in connection with a look-alike product, the unfair acts of inducing, encouraging or contributing to the infringement were enjoined, and not the copying of the product appearance.

Petitioners' sale of drug products imitating the appearance of respondent's CYCLOSPASMOL product can also not be enjoined on the ground that such copying constitutes or contributes to passing off by pharmacies and hence "false designations of origin" in violation of Section 43(a) of the Lanham Act. Respondent established neither of the requisite elements of a claim under §43(a) arising out of the simulation of a product, i.e., that the appearance of the product is non-functional and has acquired secondary meaning. On the contrary, petitioners introduced substantial evidence that was found credible by the trial court demonstrating the functional nature of the appearance of respondent's products and the valid policy considerations which motivated petitioners to copy that appearance.

One of the two products of respondent at issue herein, the pale blue 200 mg. CYCLOSPASMOL capsule, was sold in that very appearance for many years during the time when respondent owned a patent on cyclandelate and no

other manufacturer could sell a cyclandelate product in the United States. Thus, any significance in terms of source identification that the appearance of the pale blue capsules may have to consumers was developed during the term of respondent's patent monopoly. Enjoining petitioners from copying the appearance of that product of respondent after the patent owned by respondent on the drug itself expired is prohibited by the holding of this Court in *Kellogg Co.* v. *National Biscuit Co., Inc.*, 305 U.S. 111 (1938), which viewed such a prohibition as in the nature of an extension of the patent monopoly beyond its legal term.

The Second Circuit relied on evidence that a small number of professionals, specifically pharmacists, either legally substituted petitioners' generic products for that of respondent, or mislabeled prescription bottles containing the generic products as respondent's CYCLOSPASMOL product, in support of its ruling that petitioners had contributed to the infringement of the CYCLOSPASMOL trademark and thus could be prohibited from selling a look-alike product even to the vast majority of pharmacies throughout the country who do not engage in such illegal and unscrupulous practices. This Court, however, has held in cases such as *Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977), and *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) that improper acts committed by individual professional practitioners such as pharmacists and lawyers do not provide a basis for a blanket prohibition against practices that are essentially in the public interest. Petitioners established at trial that the sale of look-alike generic equivalents of more expensive branded drugs is indeed in the public interest and the Court

of Appeals should not have enjoined such a practice merely because of the improper actions of a few pharmacists who purchased petitioners' products. This is particularly the case when pharmacists who commit those improper acts are subject to criminal and civil penalties, including loss of license.

POINT I

Copying of the Unpatented and Uncopyrighted Appearance of a Product Cannot Be Barred on the Ground that Such Copying Contributes to the Infringement of a Registered Word Trademark by Purchasers.

The Second Circuit, scarcely paying lip service to the detailed findings of fact made by the district court after an extensive trial, held that the evidence in this case established that petitioners could reasonably anticipate that their generic cyclandelate products, sold in capsules of identical color, size and shape to the respondent's branded cyclandelate products, would be sold by a substantial number of druggists under respondent's registered trademark CYCLOSPASMOL (Pet. App. 82a). The Second Circuit also cited the petitioners' use of advertising comparing the prices of CYCLOSPASMOL brand cyclandelate and petitioners' generic cyclandelate products as an additional factor contributing to the "likelihood" that pharmacists would either illegally substitute the generic products when a prescription required CYCLOSPASMOL capsules or simply mislabel the generic product as CYCLOSPASMOL in instances where substitution of the generic was permitted (*id.*). Accordingly, the court held (Pet. App. 86a) that petitioners should be enjoined from selling their look-alike

cyclandelate products on the ground that the sale of such products constitutes contributory trademark infringment under Section 32 of the Lanham Act, 15 U.S.C. §1114.

Petitioners submit that even if the situation were as stated by the Second Circuit, the fact that pharmacists were using petitioners' look-alike products to commit acts of trademark infringement cannot serve as a basis for enjoining the copying of the appearance (principally the surface coloration) of the respondent's products, which appearance is neither patented nor copyrighted, and this is so regardless of whether or not appellants can be said to have contributed to or suggested such trademark infringement.

The applicable law relating to contributory trademark infringement under Section 32 of the Lanham Act was extensively discussed by the Second Circuit in *Ives II*[2] (Pet. App. 34a-36a). The court held that a manufacturer or wholesaler would be liable under Section 32 of the Lanham Act,

> "if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and

2. For the sake of convenient reference, the decisions below will henceforth be referred to as follows:

Ives I—The district court decision denying a preliminary injunction, reported at 455 F.Supp. 939 (E.D.N.Y. 1978).

Ives II—The Second Circuit decision affirming the denial of a preliminary injunction, reported at 601 F.2d 631 (2d Cir. 1979).

Ives III—The district court decision after trial, reported at 488 F.Supp. 394 (E.D.N.Y. 1980).

Ives IV—The Second Circuit opinion reversing the district court's decision on the merits, reported at 638 F.2d 538 (2d Cir. 1981).

> apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described."

(Pet. App. 35a). The court cited with approval the criteria for a finding of contributory trademark infringement set forth by Judge Wyzanski in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D. Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir. 1947), *cert. denied*, 332 U.S. 809 (1947). In that case, Judge Wyzanski held that before a party can be liable as a contributory infringer, he must have knowledge that the persons to whom he supplies the instrument by which the latter commit the infringement will or can reasonably be expected to commit the infringement with the instrument supplied. "The test is whether wrongdoing by the purchaser 'might well have been anticipated by the defendant.'" *Id.* (citation omitted).

Applying the Second Circuit's and Judge Wyzanski's definition of the tort of contributory trademark infringement, the trial court in this case found that:

> ". . . defendants did not suggest, even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark Cyclospasmol. Nor did Ives show that defendants continued to sell the generic drug to pharmacists who defendants knew or had reason to know were engaging in such a practice. 601 F. 2d at 636."

(Pet. App. 59a).

Without even applying the "clearly erroneous" test to these findings of fact by the trial court, the Court of Appeals in *Ives IV* nevertheless reversed the district court on

the contributory trademark infringement issue, finding that the petitioners "could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage." (Pet App. 82a). The court further held that petitioners' sale of their products under these circumstances amounted to a suggestion, at least by implication, that the druggists engage in such misconduct (Pet. App. 82a-83a).[3]

Aside from the incorrect and improper reversal by the Court of Appeals of the findings of fact and conclusions of law made by the district court in following the guidelines set down in *Ives II*,[4] it is submitted by petitioner Premo that under the strong public policy enunciated by this Court in cases such as *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp.* v. *Day-Brite Lighting Co.*, 376 U.S. 234 (1964) favoring copying of the unpatented and uncopyrighted appearance of articles of manufacture in order to promote free and open competition, the sale by petitioners herein of look-alike generic cyclandelate products could not be enjoined even if they were indeed

3. It is interesting to note that the Second Circuit in *Ives IV* thus consolidated the two alternative criteria for a finding of contributory trademark infringement set forth in *Ives II* into one criterion. Apparently, according to the *Ives IV* court, once it is found that a seller could reasonably anticipate that the purchaser would use the product to infringe, the seller is viewed, without having committed any additional act of inducement, as having suggested that the purchaser engage in this improper conduct.

4. See Judge Mulligan's dissenting opinion in *Ives IV* on this point (Pet. App. 90a-91a).

guilty of suggesting, inducing or contributing to trademark infringement by retail pharmacists.

The *Sears* and *Compco* cases were, technically, decided on grounds of the supremacy of federal patent and copyright law over state unfair competition law, and this Court held that a state could not enjoin, under the guise of unfair competition, the copying by a competitor of the appearance of an article which was not patented or copyrighted (either because not statutorily subject to patent or copyright, because no such protection was secured by the manufacturer or originator thereof or because any patent or copyright protection had expired). The policy enunciated in those cases strongly favoring the unrestricted copying of unpatented and uncopyrighted articles is applicable to the facts of the case at bar.

In *Sears,* for example, the Court rejected the argument that the manufacture by the defendant Sears of an article which looked exactly like Stiffel's unpatented lamp was likely to cause confusion to consumers and thus should be enjoined. Acknowledging that there could be confusion between two such nearly identical articles, the Court nevertheless stated:

> "But mere inability of the public to tell two identical articles apart is not enough to support an injunction against copying or an award of damages for copying that which the federal patent laws permit to be copied."

376 U.S. at 232. The point was even more forcefully made in *Compco,* wherein the Court expressed the following views regarding the copying of an unpatentable article:

> "Under the federal patent laws it is, therefore, in the public domain and can be copied in every detail by who-

> ever pleases. It is true that the trial court found that the configuration of Day-Brite's fixture identified Day-Brite to the trade because the arrangement of the ribbing had, like a trademark, acquired a 'secondary meaning' by which that particular design was associated with Day-Brite. *But if the design is not entitled to a design patent or other federal statutory protection, then it can be copied at will.*"

376 U.S. at 237-38 (emphasis supplied).

The Court of Appeals in *Ives IV* purported to hold only that the copying of the appearance of respondent's capsules, which appearance is not and has never been the subject of patent or copyright, should be enjoined under Section 32 of the Lanham Act because the sale of such look-alike products contributed to infringement of the trademark CYCLOSPASMOL associated with the respondent's products. The Second Circuit did not rule that such an injunction would lie under state unfair competition law, and therefore no issue of conflict with federal patent policy is squarely presented.[5] But it is submitted that under the doctrine set forth in the *Sears* and *Compco* cases, only the constitutionally mandated and statutorily created limited exceptions to the general rule of free and open competition, *viz.*, patents and copyrights, can provide the basis for an injunction against copying the appearance of a product. Such copying cannot be barred (as was held in *Ives IV*) merely because of the possibility that it assists or encourages purchasers to independently commit unfair compet-

5. The appearances of respondent's products at issue herein have neither been federally registered nor are they registrable as trademarks under the provisions of the Lanham Act. In fact, respondent never made any direct claim and there is no finding by any court below that the appearances of respondent's products are themselves trademarks in any sense.

itive acts such as infringement of a trademark applied to the article.

At the end of the majority opinion in the *Sears* case, this Court acknowledged that states could protect businesses in the use of their trademarks, labels and trade dress in order to prevent passing off of goods or deception of purchasers. But the Court emphasized that copying of the article itself could not be enjoined by a state nor could damages be awarded for such copying. *Id.* at 232-33. The dictum in *Sears* that a manufacturer could be enjoined (whether under state or federal law) from misleading purchasers as to the source of a product does not support the Second Circuit's ruling in this case that petitioners, who never deceived or confused anyone as to the source of their products, could be enjoined from copying the appearance of respondent's product merely because a small number of retail pharmacists allegedly utilized the look-alike products to commit unlawful acts. This is particularly the case because petitioners always took affirmative steps to ensure that their customers, who are drug wholesalers, distributors and retailers, were fully aware of the source of petitioners' products.[6]

The Second Circuit cited no authority for the proposition that the type of copying described in *Sears* and *Compco* as permissible under virtually all circumstances could be enjoined because purchasers of the look-alike products allegedly utilized the same to violate Section 32 of the Lan-

6. Petitioners sell their products in bottles which clearly identify the source of the product. Although consumers do not see the labeled bottles, it can in no way be said that petitioners pass off their products on *their* customers or deceive their customers as to the source of the goods.

ham Act. The only cases cited by the *Ives IV* court[7] which allegedly enjoined "similar activity" as "enabling druggists to defraud by palming off" (Pet. App. 83a) are cases which did not deal with §32 at all and are clearly distinguishable either on their facts or because the relief granted fell far short of enjoining copying of appearance.

In *Upjohn* v. *Schwartz, supra,* it was found that the defendant and his agents had actively counseled customers to illegally substitute his prescription drug products for the plaintiff's. The Court of Appeals held that the manufacturer's suggestion to the druggists that the products could be substituted for a competitor's product was itself a type of passing off and unfair competition. Even so, defendant was not enjoined from simulating the appearance of the drug products because the court held (246 F.2d at 256) that the plaintiff had no monopoly "on a capsule or a tablet of a particular size, shape or color." The defendant was enjoined only from representing or suggesting to anyone that his products could be substituted for pharmaceutical products of other manufacturers having a similar appearance when a prescription specifically called for the products of the other manufacturers.[8] The defendant was also re-

7. *Upjohn Co.* v. *Schwartz,* 246 F.2d 254 (2d Cir. 1957); *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.,* 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds,* 579 F.2d 386 (3d Cir. 1978); *E.R. Squibb & Sons, Inc.* v. *Premo Pharmaceutical Labs., Inc.,* 195 U.S.P.Q. 545 (S.D.N.Y. 1977); *Smith Kline & French Laboratories* v. *Broder,* 125 U.S.P.Q. 299 (S.D. Tex. 1959).

8. It is significant that at the time of the *Upjohn* decision and several other cases involving the passing off or illegal substitution of one pharmaceutical product for another, there were no state generic substitution laws which permitted the substitution of a generic version of a branded medication prescribed by the physician. Before these laws were enacted, the pharmacist had to fill a prescription as

(footnote continued on next page)

quired to attach to his bottles or containers a notice that the contents were not to be sold or dispensed as the product of the plaintiff. Imitation of appearance was not prohibited by the *Upjohn* court; only the unlawful express suggestion of substitution was enjoined. Furthermore, the court did not deal with the issue of contributory trademark infringement or Section 32 of the Lanham Act and certainly did not hold that copying of the appearance of the products could be enjoined because it might in itself induce such infringement.

E.R. Squibb & Sons, Inc. v. *Premo Pharmaceutical Labs., Inc., supra,* involved the copying of the *package* dress of one of the plaintiff's products by the defendant. The defendant was ultimately enjoined from copying the appearance of plaintiff's package because it had acquired a secondary meaning, i.e., was recognized by consumers as identifying the product of a particular manufacturer whom they relied on; thus, the sale of a similar product in a colorably similar trade dress was likely to cause confusion of consumers. There was no issue of imitation of the appearance of the product itself or of trademark infringement in that

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it was written and if, as most physicians were wont to do, the prescription was written for a branded drug product, no other product could be legally substituted therefor. Presently, however, most states have enacted laws which permit the substitution of generic equivalents (see, e.g., the discussion of the New York generic drug substitution law in the district court preliminary injunction opinion (Pet. App. 8a)), usually on the condition that the physician consent to the substitution of a generic equivalent, and thus petitioners committed no impropriety in pointing out to their customers that their product was a generic equivalent to respondent's CYCLOSPASMOL. In fact, as Judge Mulligan observed in his opinion dissenting from the holding of the Second Circuit in this case (Pet. App. 90a, n.4) "it would seem that juxtaposition of the generic and brand name drug [in advertising and promoting generic products] would be imperative for generic manufacturers to compete effectively."

case, either direct or contributory, nor was the defendant enjoined from copying the appearance of the product that was contained in the package. *Squibb*, therefore, has no bearing on the issues presented in this case and decided by the Second Circuit.

In *Smith Kline & French Laboratories* v. *Broder*, *supra*, cited by the *Ives IV* court, the defendant, who had imitated the appearance of the plaintiff's pharmaceutical products and had pointed out the equivalence of the parties' respective products in advertising, using the plaintiff's trademarks in that connection, was found guilty of, *inter alia*, contributory trademark infringement. A very important fact which distinguishes the *Broder* case from the case at bar is that in 1959, when *Broder* was decided, generic drug substitution for a brand name drug was outlawed in virtually every state, including Texas (the law of which was applied in *Broder*). As the district court in that case stated:

> "Substitution by retail druggists of another drug, or the product of another manufacturer, than that called for by the physician's prescription, is an unethical practice in the drug business, and is criminal in this State, as well as many others. It is, however, practiced in many instances, there being a financial inducement thereto, in that the imitative drug usually sells for a fraction of the price which the genuine and well advertised product commands."

125 U.S.P.Q. at 302.

Today, as discussed previously,[9] most states, including the State of New York, permit and even encourage the substitution of generic equivalents for branded drugs as

9. See footnote 8, *supra*.

long as the physician indicates on his prescription that he consents to that substitution. Thus, whereas the comparative advertising and use of the plaintiff's trademarks in the *Broder* case could have had no legitimate purpose, the petitioners herein merely exercised their right to use truthful comparative advertising to promote the legitimate ends of generic drug substitution. In fact, as Judge Mulligan noted in his dissent in *Ives IV*, "it would seem that juxtaposition of the generic and brand name drug [in advertising literature] would be imperative for generic manufacturers to compete effectively" (Pet. App. 90a, n.4).

Even *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc., supra*, wherein the district court enjoined the sale of look-alike prescription drug products, is of no precedential value for the Second Circuit decision in the present case because it was decided under §43(a) of the Lanham Act and the New Jersey unfair competition law.[10] No issue of contributory trademark infringement was raised or decided in that case.

All cases which preceded *Ives IV*, and which were discussed by the Second Circuit, relating to the sale of look-alike drug products (or drug products in infringing packages) are distinguishable from the case at bar in very substantive, and not merely formalistic, respects. In each of the cases discussed above and all other related cases, the courts either held that the appearance of the product or packaging itself had acquired secondary meaning and that the copying thereof therefore constituted passing off, or merely enjoined the *ancillary* unfair practices, such as the

10. The applicability of §43(a) to the present case will be discussed in greater detail below (see pp. 20a-26a, *infra*).

counseling of illegal substitution, without disturbing the defendant's right to sell a product substantially identical in appearance to that of the plaintiff. In no case did a court enjoin a party from copying the appearance of a drug product on the ground that such copying might somehow encourage or contribute to infringement of the brand name associated with the product.[11]

It should be noted, in addition, that petitioners herein at no time committed unfair and predatory practices of the type perpetrated by the defendant in *Upjohn*. The only practice of the petitioners which the Second Circuit in *Ives IV* could point to as allegedly improper, beyond the mere copying of appearance, was the use of catalogs which described the appearance of the generic cyclandelate products and listed the price of those products in comparison with the price of CYCLOSPASMOL, utilizing the respondent's registered trademark in making that comparison. The use of these catalogs by the petitioners, according

11. Other cases where courts held the defendants guilty of contributory infringement involved factual situations quite different from that in the case at bar. For example, *Corning Glass Works* v. *Jeannette Glass Co.*, 308 F.Supp. 1321 (S.D.N.Y.), *aff'd*, 432 F.2d 784 (2d Cir. 1970) dealt with the simulation by the defendants of a distinctive ornamental feature of the plaintiff's ovenware which had acquired great secondary meaning among consumers, and the use by defendant of an infringing trademark for its products. In *Stix Products, Inc.* v. *United Merchants & Mfrs., Inc.*, 295 F.Supp. 479 (S.D.N.Y. 1968), distinguished by the district court in *Ives I* (Pet. App. 12a-13a), the defendant manufacturer originated and actively engaged in a scheme to facilitate the palming off by retailers of its products as those of the plaintiff. In *Stewart Paint Mfg. Co.* v. *United Hardware Distributing Co.*, 253 F.2d 568 (8th Cir. 1958), the defendant, a wholesaler who had once purchased paint from the plaintiff under the latter's trademark, terminated the contract and began to use that trademark, as well as other distinctive features of the plaintiff's product, in sales of paint purchased from another manufacturer.

No evidence of any such acts by petitioners was introduced in this case.

to the court, created an even greater likelihood that druggists would infringe the CYCLOSPASMOL trademark by applying it to prescription bottles containing the generic products (Pet. App. 82a).

Even if the use by petitioners of catalogs of the type described by the Second Circuit was improper, the Court of Appeals should not have mandated relief against copying the unprotectable appearance of respondent's products, but, instead, as the same court did in *Upjohn*, should have merely enjoined the alleged unfair practices related to the catalogs.

In reality, the Court of Appeals could not even have properly held that petitioners' advertising practices were enjoinable. Petitioners' products are therapeutically equivalent to respondent's CYCLOSPASMOL brand cyclandelate, as found by the district court (Pet. App. 58a) and not challenged by the Court of Appeals (Pet. App. 75a). Thus, under established law, petitioners can legitimately represent that equivalency in their advertising, even though making use of respondent's registered trademark to compare the products in all respects, whether as to appearance, price, or quality. Several cases decided under Section 43 (a) of the Lanham Act emphasize the point that if a party has a right to copy something which is in the public domain, he has the right to tell the public that his product is a copy of, and equivalent to, the well-known brand and use the competitor's trademark in making that legitimate comparison.

In *Smith* v. *Chanel, Inc.*, 402 F.2d 562, 567-68 (9th Cir. 1968), it was alleged that Smith violated §43(a) by ad-

vertising his perfume products as being duplicates of Chanel's famous "No. 5" and other perfumes. The court refused to grant relief, stating, *inter alia*:

> "Since appellees' perfume was unpatented, appellants had a right to copy it, as appellees concede. There was a strong public interest in their doing so, '[f]or imitation is the life blood of competition. It is the unimpeded availability of substantially equivalent units that permits the normal operation of supply and demand to yield the fair price society must pay for a given commodity.' American Safety Table Co. v. Schreiber, 269 F.2d 255, 272 (2d Cir. 1959). *But this public benefit might be lost if appellants could not tell potential purchasers that appellants' product was the equivalent of appellees' product. 'A competitor's chief weapon is his ability to represent his product as being equivalent and cheaper* * * *.'* Alexander, Honesty and Competition, 39 So.Cal.L.Rev. 1, 4 (1966). The most effective way (and, where complex chemical compositions sold under trade names are involved, often the only practical way) in which this can be done is to identify the copied article by its trademark or trade name. *To prohibit use of a competitor's trademark for the sole purpose of indentifying the competitor's product would bar effective communication of claims of equivalence.* Assuming the equivalence of 'Second Chance' and 'Chanel No. 5,' the public interest would not be served by a rule of law which would preclude sellers of 'Second Chance' from advising consumers of the equivalence and thus effectively deprive consumers of knowledge that an identical product was being offered at one third the price."

(emphasis supplied).

Similarly, in *Societe Comptoir de L'Indus., etc.* v. *Alexander's Department Stores, Inc.*, 299 F.2d 33, 36 (2d

Cir. 1962), the defendant had used plaintiff's trademarks "DIOR" and "CHRISTIAN DIOR" in promoting their copies of original fashion designs by the plaintiff. Relief was sought under Section 43(a) of the Lahnam Act. The court stated succinctly that:

> "The Lanham Act does not prohibit a commercial rival's truthfully denominating his goods a copy of a design in the public domain, though he uses the name of the designer to do so."

Finally, in *Saxony Products, Inc.* v. *Guerlain, Inc.*, 513 F.2d 716 (9th Cir. 1975), the court held that a manufacturer of perfume could advertise that its product was similar to Guerlain's "SHALIMAR" product even though "SHALIMAR" was a registered trademark. The court explained that there could be no violation of §43(a) merely through the use of a competitor's trademark, provided that the representations made were accurate and that there was no likelihood that consumers would be confused as to the source of origin of the respective products.

The promotional practices characterized by the Court of Appeals as suggesting and encouraging trademark infringement by retail pharmacists thus were wholly proper and can neither be enjoined in themselves nor be treated as supporting a finding that petitioners "suggested, even if only by implication" (*Ives II*, Pet. App. 35a) that pharmacists improperly apply the CYCLOSPASMOL trademark to petitioners' generic products.

In short, in view of the strong public policy enunciated by this Court in *Sears* and *Compco* and in light of other relevant case law on copying the appearance of products and on contributory trademark infringement, petitioners

cannot be held guilty of violating Section 32 of the Lanham Act on the ground of contributing to the infringement of a registered trademark merely by selling products which simulate the unpatented and uncopyrighted appearance of the respondent's products.

POINT II

Copying by the Appellants of the Appearance of the Respondent's Product Cannot Be Enjoined on the Ground that Such Copying Constitutes or Contributes to a Violation of Section 43(a) of the Lanham Act.

Although the Second Circuit in *Ives IV* purported to rest its decision on the ground of contributory trademark infringement by petitioners in violation of Section 32 of the Lanham Act, it analogized petitioners' conduct to activity that was enjoined as passing off or the inducement of passing off in cases such as *Upjohn, Merrell-National, Squibb,* and *Smith Kline, ubi supra.* Furthermore, the three district court and Court of Appeals decisions herein which preceded *Ives IV* extensively discussed the issue of whether the sale by petitioners of their look-alike products constituted a violation of Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), which was the principal claim asserted by respondent in all phases of this litigation below.[12] Petitioner Premo deems it appropriate to briefly address these questions to demonstrate that not only can petitioners not be enjoined from selling look-alike cyclandelate capsules on the grounds that such sales contribute to the infringement of respondent's trademark CYCLOSPASMOL, but they can also not be enjoined on the theory that such sales either induce passing off by pharmacists or constitute passing off

12. *See* Judge Mulligan's comment on this point at Pet. App. 86a, n.1.

in themselves, and hence "false designations of origin" in violation of §43(a).

As the Court of Appeals correctly held in *Ives II*, in order to establish a right to relief under Section 43(a) of the Lanham Act for simulation of the appearance of a product, it must be established that the appearance, in this case the color of respondent's capsules, is nonfunctional and has acquired secondary meaning. The Second Circuit also held that rights to protection from copying under §43(a) do not conflict with, and cannot be barred by, this Court's ruling in *Sears, supra*, and *Compco, supra* (Pet. App. 48a-49a).[13]

13. This Court has never ruled on the question of whether the policy enunciated in *Sears* and *Compco*, that copying of the appearance of an article of manufacture can be restricted only in accordance with the federal patent and copyright laws, can be circumvented by a claim that the appearance of an article is associated by consumers with a particular source and thus the copying thereof constitutes a false designation of origin or other false representation within the meaning of Section 43(a) of the Lanham Act. It is respectfully submitted that the use of §43(a) to preclude the copying of the unpatented and uncopyrighted appearances of products eviscerates the holding in *Sears* and *Compco*, although that holding is ostensibly directed only at *state* unfair competition laws. Under *Sears*, a party cannot complain of the simulation of its product by a competitor on the grounds of common law unfair competition (or unfair competition under a state statute). But according to the Second Circuit's view, a plaintiff need only allege that its product and its competitor's product are sold in interstate commerce to convert the very same act which cannot be enjoined under state law because of *Sears* into one interdictable under §43(a). Since few companies of any size sell their products solely in intra-state commerce, this interpretation of §43(a) defeats the basic policy of the *Sears* and *Compco* decisions.

Petitioner Premo suggests that even in a case where there is substantial evidence that the mere simulation of the appearance of an article is tantamount to a "false designation of origin" or "false representation in commerce" within the meaning of §43(a), relief under that section should be limited to compelling the imitator to use labeling and advertising to clearly indicate the source of its product to the public, and, in appropriate cases, to affirmatively disassociate its product from the competitor. In addition, the imitator could certainly be enjoined from any practices tending to foster confusion of the public as to source. But no blanket injunction against the copying of appearance should be issued under §43(a) or any other provision of the Lanham Act.

Relief under § 43(a) was denied to the respondent at all stages of this litigation prior to *Ives IV* because, *inter alia*, respondent had not established that the colors of its capsules had acquired a secondary meaning identifying the products' source and that consumers were moved to purchase the products because of that source (*Ives I*, Pet. App. 23a-34a; *Ives II*, Pet. App. 51a; *Ives III*, Pet. App. 64a-69a). This finding that no secondary meaning had been established by the respondent in the colors of its products was not disturbed by the Court of Appeals in *Ives IV* and thus must be accepted as controlling at this stage.

Similarly, it was held in the earlier decisions below that respondent did not establish a right to relief under the New York law of unfair competition (*Ives I*, Pet. App. 25a-27a; *Ives II*, Pet. App. 51a-52a; *Ives III*, Pet. App. 69a-70a) and that ruling was not disturbed by the Court of Appeals in *Ives IV*.

Because the appearance of the respondent's product has not acquired secondary meaning and thus does not serve to identify the source of the product, the sale by petitioners of generic products cannot be said to constitute passing off in itself. Moreover, petitioners affirmatively avoid any possibility that their customers could be deceived as to the source of petitioners' products by clearly labeling bottles of their products so that their customers make no mistake as to the origin of these goods. Nevertheless, the Second Circuit in *Ives IV*, in its discussion of the alleged §32 violation, at least impliedly characterized petitioners' sales practices as enjoinable because the sale of look-alike prescription drug products induces passing off by pharmacists

(aside from contributing to the pharmacists' infringement of respondent's registered trademark by the use of the same on the prescription bottles). In other words, one can infer that the *Ives IV* Court was of the opinion that the mere sale of these look-alike capsules was likely to confuse consumers accustomed to the appearance of the brand name product, whether or not the CYCLOSPASMOL trademark was applied to the prescription bottles by pharmacists.

Any contention that copying of the uncopyrighted and unpatented appearance of respondent's drug products could be enjoined on the ground that such copying encouraged, induced, or suggested to purchasers that they pass off these products on unwitting customers runs afoul of the policy of free competition set forth in *Sears* and *Compco* (and discussed previously[14]) to at least as great a degree as the assertion that such copying could be enjoined because it contributes to infringement of a registered trademark. Even before the *Sears* and *Compco* decisions, however, courts faced with situations where the appearance of prescription drug products had been copied and passing off at the retail level had allegedly occurred did not issue injunctions against the copying of the unprotectable appearance of the product but instead sought to restrain the ancillary predatory or unfair competitive practices which were directly responsible for encouraging passing off.

In *William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526 (1924), a case dealing, like the present one, with the color of a drug product, this Court held that plaintiff Lilly had no right to stop the defendant from selling a product looking exactly like Lilly's. Although the Court disap-

14. See pp. 8-11, *supra*.

proved of the suggestions made by the defendant's salesmen that the defendant's products could be substituted for Lilly's without danger of detection on prescriptions and on orders for the Lilly product, and the Court further condemned the defendant's pointing out to druggists the identity of the two preparations and the enhanced profits to be made by selling the defendant's product because of its lower price, the Court would not grant an injunction against the sale of the look-alike drug product but instead limited its relief to interdicting the predatory and unfair competitive practices of the defendant which were inducing illegal substitution and passing off.

The *Ives II* opinion contains an excellent discussion of the *Warner* case as well as several other cases involving copying of the appearance of drug products wherein the courts refused to enjoin the copying itself but instead directed their injunctive relief against the express palming off of the accused products or practices such as direct inducement of substitution and passing off by the defendants or their agents (Pet. App. 36a-42a). These cases include *Smith Kline & French Laboratories* v. *Clark & Clark*, 157 F.2d 725 (3d Cir. 1946), *cert. denied*, 329 U.S. 796 (1946) (actual palming off enjoined and defendants required to stamp their tablets with a distinguishing mark); *Norwich Pharmacal Co.* v. *Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960) (court refused to enjoin copying of the color of plaintiff's medication because there was no proof of secondary meaning, palming off, actual deception or appropriation of another's property); and *Upjohn Co.* v. *Schwartz*, *supra*.

If petitioners were guilty of ancillary unfair competitive practices, as were the defendants in cases such as

Warner, supra, and *Upjohn, supra,* an injunction might perhaps lie against those specific practices, but under no circumstances could petitioners be enjoined from copying the respondent's capsule colors on the facts of the present case.

With respect to the requirement for a valid cause of action under §43(a) that the appearance of the product, the imitation of which is sought to be enjoined, must be non-functional, the district court clearly found that the colors of petitioners' products are functional in several respects (*Ives III,* Pet. App. 63a-64a).

The trial court based its finding of functionality on the evidence put in by petitioners which demonstrated the following: First, many elderly patients associate the appearance of their medication with its therapeutic effects and, once they have become accustomed to the brand name drugs' appearance, they will be reluctant and may be caused anxiety when asked to accept a generic equivalent in an unfamiliar appearance. Second, many patients (in particular the elderly, who are the main consumers of cyclandelate) co-mingle their drugs of different types in a single container and then rely on the appearance of each drug to follow their doctors' instructions. It is, therefore, important that a brand name drug and its generic therapeutic equivalents have a uniform appearance so that doctors can use the appearance of the drug in communicating instructions to patients regarding their medications. Third, to a limited extent, color is useful to doctors and hospital emergency rooms in identifying drugs in overdose cases. The color of the capsule frequently provides a clue in the difficult and hurried effort to determine what a patient has ingested (Pet. App. 63a).

There was further evidence in the record below that one of the petitioners (Inwood Laboratories) had attempted to sell a generic cyclandelate product in a color totally dissimilar to respondent's products, and the non-look-alike product was not accepted by hospitals, pharmacies and wholesalers (Pet. App. 63a-64a). This failed attempt to sell a generic cyclandelante product with an appearance different from respondent's CYCLOSPASMOL sharply illustrates the commercial functionality of the appearance of respondent's products.

The Court of Appeals rejected petitioners' arguments as to the legitimate reasons for their copying of the functional appearance of respondent's products as "unconvincing" (Pet. App. 85a). Judge Mulligan, however, in his dissent, properly criticized the majority's contention that no persuasive evidence of a legitimate reason for using the appearance of respondent's product was offered by petitioners (Pet. App. 90a-91a). He observed that the majority did not characterize the trial court's findings on the question of functionality and on petitioner's motivations in copying the CYCLOSPASMOL appearance as "clearly erroneous", but, instead, ignored the evidence on which the trial court relied in these respects and its findings of credibility with regard to the testimony of witnesses who appeared before it.

Petitioners respectfully submit that the trial court's findings on the question of functionality should be regarded as authoritative and that petitioners can therefore not be enjoined from the sale of their look-alike generic cyclandelate products under §43(a) because that appearance has not been proven to be non-functional; and because, as discussed previously, respondent never established that that appearance had acquired secondary meaning.

POINT III

Even if the Appearance of Respondent's Blue Capsules Were Associated by the Public with Respondent, Petitioners Could Not Be Enjoined from Copying that Appearance Because the Public Recognition Thereof Was Acquired During the Period of Respondent's Patent Monopoly.

Until April 26, 1972 respondent owned a patent which covered the drug cyclandelate and was the only manufacturer that had ever marketed that drug in the United States (Pet. App. 56a; 75a). Respondent began to use the pale blue color of one of its CYCLOSPASMOL products (the 200 mg. capsule), which was copied by petitioners and which is at issue in this case, during the term of the patent (Pet. App. 57a). Because cyclandelate capsules originated with respondent and no other manufacturer during the term of the patent, it is logical to assume that consumers may have associated the pale blue color of the product with a capsule containing CYCLOSPASMOL brand cyclandelate, *solely because those were the only cyclandelate capsules available on the market and prescribed to patients.* Thus, even if respondent had been able to establish at trial that the appearance of its 200 mg. product was associated by the public with CYCLOSPASMOL brand cyclandelate, the holding of this Court in *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111 (1938) would bar the granting of relief to respondent against the copying of that appearance.

In *Kellogg*, the plaintiff, National Biscuit Co., had at one time owned a design patent on the pillow shape of its shredded wheat product. Upon expiration of the patent,

the defendant made shredded wheat in the pillow shape and was charged with unfair competition. The Supreme Court reversed the lower court decision granting relief, stating as follows:

> "The plaintiff has not the exclusive right to sell shredded wheat in the form of a pillow-shaped biscuit —*the form in which the article became known to the public.*
>
> • • •
>
> "Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights in a form in which the public has become accustomed to see the article and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind."

305 U.S. at 119-20 (emphasis supplied).

The rationale of the *Kellogg* case applies with full force to the case at bar. The respondent herein should no more be permitted to secure protection for the blue color of its 200 mg. CYCLOSPASMOL capsules than it could for the generic name of the product, i.e., cyclandelate. Like the pillow-shaped appearance of National Biscuit Co.'s shredded wheat, the color of respondent's capsules developed any significance they may have to consumers during the period when respondent held a legal monopoly in the cyclandelate market under its patent. Granting an injunction against copying the appearance of respondent's capsules controverts the principle expressed by this Court in *Kellogg* as follows:

> "Sharing in the goodwill of an article unprotected by patent or trademark is the exercise of a right pos-

sessed by all—and in the free exercise of which the consuming public is deeply interested."

Kellogg, supra at 122, quoted in *Sears, Roebuck & Co.* v. *Stiffel Co., supra* at 231.

POINT IV

Copying of the Appearance of Respondent's Products by Petitioners Cannot Be Enjoined on the Basis of Illegal Acts Committed by a Small Number of Licensed Professionals Who Utilize Those Products.

In reversing the district court's finding in *Ives III* that insufficient evidence had been introduced by respondent at trial to establish a violation of Section 32 of the Lanham Act, the Second Circuit in *Ives IV* relied on certain shopping surveys that were conducted by respondent which allegedly showed that a significant number of retail pharmacists infringed the registered trademark CYCLOSPASMOL by mislabeling petitioners' generic products with that trademark (Pet. App. 81a-82a).

In fact, as argued by Judge Mulligan in dissent (Pet. App. 88a), only 10 out of 83 pharmacies shopped were found to have committed any improper acts. Moreover, 9 out of the 10 druggists involved obviously had no intention of passing off the generic products as the brand name drug as evidenced by the fact that they specifically advised the patient purchasing the drug *that they were receiving a generic product* (*id.*). In addition, 5 out of the 10 druggists who used the word "CYCLOSPASMOL" on the prescription vial label also included the word "generic" or its abbreviation before or after the respondent's trademark, in-

dicating their desire to convey to the patient that a generic version of respondent's CYCLOSPASMOL product was being dispensed (*id.*). Only one pharmacist actually passed off a generic cyclandelate product as respondent's CYCLOSPASMOL when the prescription presented did not permit substitution of a generic, and only that pharmacist charged the higher brand name price for the generic and thus reaped any profit from his improper actions (*id.*).

The Second Circuit relied on this rather meager showing of instances where the respondent's CYCLOSPASMOL trademark was infringed by pharmacists selling petitioners' generic products in ruling that petitioners should be enjoined from copying the appearance of CYCLOSPASMOL. There was not even any evidence that the trademark infringement by the pharmacists was in any way related or tied to the fact that these generics had the same appearance as CYCLOSPASMOL. It is far more likely that at least the nine pharmacists who informed the patients that they were receiving a generic mislabeled the product as CYCLOSPASMOL or "CYCLOSPASMOL generic" because they were unaware of the correct generic name or because of a misunderstanding of the law, and that same ignorance or misunderstanding would have prevailed no matter what colors petitioners' generic products were sold in.

In any case, this Court has held that unscrupulous or improper acts committed by individual professional practitioners such as pharmacists and lawyers do not provide a basis for a blanket prohibition against practices that are essentially in the public interest. See *Bates* v. *State Board of Arizona*, 433 U.S. 350 (1977); *Virginia State Board of*

Pharmacy v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

There was evidence in this case in the form of testimony by one of respondent's own witnesses, the President of the New York State Pharmaceutical Society, that he personally knew of no illegal substitution of generic for brand name drugs and that he did not believe the practice was widespread (Pet. App. 69a; 89a, n.2). Furthermore, there was never any doubt that pharmacists who committed illicit acts such as illegal substitution or passing off of a generic drug as a brand name drug are subject to civil and criminal penalities.[15] (Pet. App. 69a).

The Second Circuit held that the fact that a few pharmacists committed these violations of state law and of their professional duty, either deliberately or out of ignorance, provided sufficient ground for enjoining petitioners from copying the appearance of respondent's CYCLOSPASMOL on the unsupported assumption that these unethical or misinformed pharmacists would be deterred from their acts if generic cyclandelate products were sold only with appearances distinguishable from CYCLASPASMOL.

It is respectfully submitted that the entire approach of the Court of Appeals to the question of how best to remedy individual instances of illegal substitution or mislabeling

15. The majority in *Ives IV* relied on the existence of six indictments in New York of pharmacists who allegedly illegally substituted and mislabeled generic cyclandelate for CYCLOSPASMOL as evidence that the practice was becoming widespread (Pet. App. 83a-84a). In fact, as Judge Mulligan noted in dissent (Pet. App. 90a), such indictments, while not proof of any illegality and not evidence of widespread illegal practices, would, if anything, help discourage other unethical pharmacists from committing similar acts.

by retail pharmacists, i.e., by enjoining the sale of look-alike cyclandelate products to all pharmacists anywhere in the country, runs counter to the approach adopted by this Court in the *Bates* and *Virginia Pharmacy* cases, *supra*, and is not at all in the public interest.

Substantial evidence was put in by petitioners at trial to establish that the sales of generic drugs with an appearance that simulates the branded drugs to which they are equivalent serves important utilitarian purposes and makes the generic products more acceptable, in particular to elderly consumers who are the main purchasers of a drug such as cyclandelate and who can least afford the higher-priced brand name drugs (see pages 25-26, *supra*). In *Ives II*, the Second Circuit itself commented that the district judge was warranted in finding some merit to petitioners' arguments that their copying of the CYCLOSPASMOL colors for their generic products was motivated by important policy considerations (Pet. App. 50a). In *Ives IV*, however, the Court of Appeals merely brushed aside the trial court's detailed findings of fact with regard to petitioners' legitimate motivations for copying and held that petitioners sold look-alike cyclandelate products only because they anticipated that such products would be acceptable to a substantial number of druggists who intended to substitute the product illegally for, or mislabel it as, CYCLOSPASMOL capsules.

The net effect of the Second Circuit decision is to preclude the public from purchasing therapeutically equivalent, lower-priced generic substitutes for CYCLOSPASMOL in the appearance to which the public has become accustomed *even when pharmacists properly dispense those*

drugs, i.e., without use of the respondent's trademark, as is true in the great majority of cases even according to the record established in this case. The Court of Appeals disregarded all applicable precedents which stress that copying of the unpatented, uncopyrighted appearance of a product cannot be enjoined even when unfair practices are committed therewith by purchasers, and also ignored this Court's holdings in the *Bates* and *Virginia Pharmacy* cases, *supra*, against the blanket suppression of commercial practices legitimate in themselves on the ground that some licensed professionals may commit improper acts by perverting or abusing those practices.[16]

Clearly, any remedy against illegal substitution or passing off by certain pharmacists should be directed against those pharmacists. At most, petitioners should be required only to provide clear warnings on their products that they are not to be sold or dispensed except in accordance with state drug substitution laws and are not to be mislabeled as respondent's CYCLOSPASMOL capsules. No further relief is justified by the facts in this case or by the applicable law.

16. Obviously, the Second Circuit in *Ives IV* believed that the practice of copying the appearance of a drug should be made unlawful. Confronted by the district court's findings, which it could not reverse as clearly erroneous, the Court of Appeals found a way to prevent the copying by resorting to Section 32 of the Lanham Act.

Conclusion

The judgment of the United States Court of Appeals for the Second Circuit appealed from herein should be reversed.

Respectfully submitted,

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IN THE

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v.

IVES LABORATORIES, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENT

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Questions Presented

1. Was the Court of Appeals correct in holding the defendants liable for contributory infringement under §32 of the Lanham Act, 15 U.S.C. §1114, and basing said liability on the fact that (a) defendants sold their prescription drug in capsules that intentionally copied the appearance of the capsules in which plaintiff's CYCLOSPASMOL brand of the drug cyclandelate had long been sold; (b) defendants' look-alike capsules were illegally substituted in prescriptions calling for the dispensing of plaintiff's drug product and otherwise passed off by pharmacists as plaintiff's CYCLOSPASMOL cyclandelate; (c) the acts of the pharmacists were reasonably foreseeable by defendants; and (d) the copying of the capsule colors made the illegal substitution and passing off more likely to occur and more difficult for patients to detect?

2. Does an injunction permitting the sale of a drug product but restricting the copying of the appearance of the capsules in which a prescription drug has been sold, which supports the federal policy of preventing unfair competition and infringement as embodied in the Lanham Act, violate in any way the federal policy of encouraging competition by allowing the copying of the subject matter claimed in patents after their expiration, or any state policy encouraging the availability of generic drugs?

Statement Pursuant to Supreme Court Rule 28.1

Respondent Ives Laboratories, Inc. is a subsidiary of American Home Products Corporation, which also has numerous other subsidiaries.

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENT

Statement of the Case

Defendants/petitioners sell a prescription drug known by the generic name cyclandelate in capsules identically copying the appearance of the distinctive blue and blue/red capsules in which plaintiff has long sold its CYCLO-SPASMOL brand of cyclandelate. Plaintiff/respondent does not dispute defendants' right to sell the drug, nor their right accurately to compare their product to plaintiff's. Plaintiff has, however, claimed that, by selling their cyclandelate in look-alike capsules, defendants (1) violate §43a of

the Lanham Act, 15 U.S.C. §1125(a), (2) are liable under New York law for unfair competition, and (3) are liable as contributory trademark infringers when pharmacists pass off the look-alike capsules as plaintiff's CYCLOSPASMOL brand of cyclandelate in violation of 15 U.S.C. §1114.

I.

The Proceedings Prior to Trial

The case was before the District Court and the Court of Appeals twice.[1] On plaintiff's Motion for Preliminary Injunction, the District Court assumed that an injunction against copying the colors of the capsules could never be granted. It held that (1) relief was precluded under federal and state law by the Supreme Court decisions in *Sears/Compco*[2]; (2) the appearance of capsules was not protectable as trade dress because the capsules were ingested; and (3) defendants could be liable for contributory infringement only if it were proved that they were accessories to the crime of illegal substitution or had conspired with the pharmacies or otherwise actively instigated or participated in their passing off. (PA 13a, 21a, 25a)

The Court of Appeals affirmed the denial of preliminary relief, but found "the case more difficult than did the district judge". (PA 30a) It unequivocally held, in a unanimous opinion written by Judge Friendly, that an injunction against the copying of the colors of a prescription drug capsule is available in certain circumstances.

On the contributory infringement claim, it characterized as the most serious wrongdoing the illegal substitution of generic cyclandelate in filling prescriptions for

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[1] The four decisions are printed in the Appendix to the Petition for Writ of Certiorari in No. 80-2182 and will be referred to as PA. The Joint Appendix is referred to as A. The trial transcript is TR.

[2] *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964); *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

CYCLOSPASMOL, and mislabelling the generic as CYCLOSPASMOL. "Intermediate" wrongdoing includes legally substituting the generic, but then mislabelling it as CYCLOSPASMOL, or giving it no name at all. (PA 34a) In order to find the defendants liable for these acts of infringement, it was not necessary to prove that they were "accessories to the crime" of illegal substitution or that they actively participated in the retailers' infringement. They would be liable, the Court held, if they suggested, even if only by implication, that generic capsules be labelled with Ives' trademark, or continued to sell capsules facilitating passing off to druggists whom they knew or had reason to know engaged in such practices. (PA 35a) Citing *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980 (D.Mass. 1946) aff'd 162 F.2d 280 (1 Cir. 1947), *cert. denied*, 332 U.S. 809 (1947), it found that the "proper criteria" for liability were whether a reasonable person would realize he had created a temptation or opportunity for wrong for "l'homme sensuel" or that he was dealing with customers he knew would be peculiarly likely to use the product wrongfully. (PA 35a)

As to the 43a claim, the Court held that there is liability for copying the colors if they are not functional, and if they had acquired secondary meaning, i.e., that consumers associate the blue and blue/red capsule colors with CYCLOSPASMOL. (PA 48a, 50a) "The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors does not seem persuasive". (PA 50a) The Court also held that, given the method of sale, Ives had no way of identifying CYCLOSPASMOL to the ultimate purchaser other than by color, and that the capsule colors may constitute trade dress, although ultimately ingested. (PA 51a) It also acknowledged that "the blue and blue/red coatings of Ives' capsules do not contribute to their efficacy; any other colors would do as well . . . the case for functionality thus depends on the evidence proffered *by defendants* . . .". (PA 49a-50a, emphasis supplied)

The Court left open the question of how New York law would strike the balance between the state unfair competition claims and the policy of the generic drug law facilitating authorized substitution. (PA 52a)

A trial to the same District Court judge who denied the preliminary injunction was then held, in which substantial additional evidence on each issue was presented.

II.

Statement of Facts

A. *The Products of Ives and the Defendants*

The plaintiff Ives Laboratories, Inc. ("Ives") is what may be called an innovator company that introduces new drugs, does the extensive research and testing necessary to obtain approval of the Food and Drug Administration for their sale, and develops market acceptance of the products. (81A, 121A) The drug at issue is a vasodilator known by the trademark CYCLOSPASMOL and the generic name cyclandelate. This product, which is sold only by prescription, is used to treat vascular diseases, many of which are associated with aging. Cyclandelate therapy is generally long term. (81A, 94A)

When Ives began selling its cyclandelate, the chemical structure of the drug's active ingredient was patented. (TR 41-2a, 572A) The patent, which issued in 1955, expired in 1972, and Ives does not dispute that others are free to produce and market the drug.

Since 1962, Ives has sold its cyclandelate, in a 200 mg. dosage form, in a vivid blue capsule. (81A) Three years after expiration of the patent, it began to sell an additional dosage, 400 mg., in a blue/red capsule.[3] (81-2A)

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[3] The Ives cyclandelate is also sold in a 100 mg. pale orange tablet, but that has not been copied and is not therefore in issue except insofar as it demonstrates that cyclandelate may be sold in a form other than capsules. (84A)

Although there are many products in the vasodilator category other than cyclandelate, none are sold in capsules similar in color to those used by Ives. (95A, 104A) The colors were arbitrary when selected, were not mentioned in the patent, and are not dictated by the appearance of the drug, which is a white powder. (82-3A) The colors, and the trademark CYCLOSPASMOL, were selected to identify the product as Ives' product. (82A)

Ives has made extensive sales, exceeding $106,000,000, and done considerable promotion of CYCLOSPASMOL cyclandelate. (92-3A) To develop its professional acceptance, medical sales representatives have continually visited physicians, hospitals and pharmacies, and there have been print advertisements and direct mailings to professionals. (86A, 100-101A) File cards describing the therapy and indicating the colors of CYCLOSPASMOL have been left with physicians for use and reference, and the product is shown in color in the Physicians' Desk Reference, ("PDR") a widely used reference tool. (90A, Pl. Ex. 15) Although prescription drugs are not advertised to patients, they have had access to information about the Ives' product. In addition to the PDR, a Consumer Guide publication for laymen has described cyclandelate and noted that CYCLOSPASMOL is Ives' trademark and that the Ives' product is sold in blue and blue/red capsules. TR 80a, 82a, Pl. Ex. 19b) Further exposure has occurred through starter samples which physicians give to their patients, in which the blue and blue/red capsules are in bottles labelled to show Ives as their source, along with the Ives' trademark "CYCLOSPASMOL®" and the generic name cyclandelate. (Pl. Exs. 7, 8, 91A) All CYCLOSPASMOL capsules are imprinted with the name Ives and a National Drug Code identification number. (82A)

The defendants are manufacturers or distributors of generic drugs which, in this and other instances, not only copy ...e active ingredient after expiration of an in-

novator's patent (a right which Ives does not challenge),[4] but also intentionally copy the appearance of the capsules or tablets in which the innovator's product has been sold and, in some instances, even its cartons.[5] In this case, the capsule colors were copied identically and every attempt was made to conceal the true source of the defendants' product. Prior to the suit, the capsules bore no marking whatsoever, and defendants, after examining the capsules, could not even identify their own products.[6] (388A, 410a, 427a) Sherry Pharmaceutical Co., Inc. ("Sherry") not only copied the capsule colors, but also used the trademark SPASMOL, until this infringement was enjoined. (PA 59a) In promotional materials, defendants have emphasized the similarity of the colors and juxtaposed listings of their products with listings of the brands of various pioneer drugs, including CYCLOSPASMOL. (TR 107-8B, 586A-650A)

B. *Passing Off and Illegal Substitution*

Prescription drugs are commonly purchased in bulk and dispensed by pharmacists who remove tablets or capsules from the manufacturers' bottles (which, in the case of cyclandelate, contain 100, 500 or 1000 capsules) and transfer them, in the smaller quantities called for in the prescription, to a pharmacy vial bearing the pharmacy's own label. (TR 26a) The pharmacist is thus an integral part of the system for distributing drugs and for identifying them to

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[4] In some instances, they copy the product and its trade dress even before expiration of the patent. See, e.g., *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3 Cir. 1980) (hereafter referred to as *SK&F* v. *Premo*) and *Hoffman LaRoche, Inc.* v. *Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980) (hereafter referred to as *Hoffman LaRoche* v. *Premo*).

[5] *E.R. Squibb & Sons, Inc.* v. *Premo Pharmaceutical Laboratories, Inc.*, 195 U.S.P.Q. 545 (S.D.N.Y. 1977).

[6] Premo, during the litigation, began imprinting the name Premo on the capsules. Inwood began imprinting the code number "258." (38A)

the consumer. It is the pharmacist who puts the name and label on the drug dispensed to the patient. A prescribing physician rarely sees what drug has been dispensed, or what it has been called. (256A, 259-60A, 214A)

Historically there have been numerous cases in which pharmacists have dispensed look-alike products instead of the branded products called for in prescriptions, and identified them with the innovator's trademark, with the apparent aim of increasing their own profits.[7] The practice was certainly known prior to passage of generic substitution laws in the 1970's. A 1979 Staff Report to the Federal Trade Commission on Drug Product Selection acknowledges that, after World War II, "some manufacturers went beyond merely encouraging pharmacists to dispense their version of a prescribed drug, and clandestinely began to manufacture 'counterfeit' drugs: products similar in size, shape and sometimes packaging to the popular brand-name drug . . . counterfeiting reached 'epidemic' proportions in the early 1950's". (FTC Report p. 144) As many as 25% of all pharmacists practiced substitution, which was then illegal, with surveys on individual products showing rates of illegal substitution as high as 40% (FTC Report p. 144).

The practice of illegal substitution and mislabelling has continued after passage of generic substitution laws.[8] In-

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[7] These include *Winthrop Chemical Co., Inc.* v. *Weinberg*, 60 F.2d 461 (3 Cir. 1932); *Smith Kline & French Laboratories* v. *Broder*, 125 U.S.P.Q. 299 (S.D. Texas 1959); *Smith Kline & French Laboratories* v. *Heart Pharmaceutical Corp.*, 90 F.Supp. 976 (S.D.N.Y. 1950); *Ross Whitney Corp.* v. *Smith Kline & French Laboratories*, 207 F.2d 190 (9 Cir. 1953) and *Pinoleum Co.* v. *Baron*, 121 Misc. 384, 201 N.Y.Supp. 44 (Sup. Ct. Kings County 1923).

[8] See, for example, *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977); aff'd on procedural grounds, 579 F.2d 786 (3 Cir. 1978); *Hoffman LaRoche* v. *Premo, supra*, p. 6 n.4; *A.H. Robins Co.* v. *Medicine Chest Corp., et al.* (including Inwood Laboratories, Inc.), 206 U.S.P.Q. 1015 (E.D. Mo. 1980) (hereafter referred to as *A.H. Robins* v. *Medicine Chest*); *SK&F* v. *Premo, supra*, p. 6 n.4; *Pennwalt Corp.* v. *Zenith Laboratories, Inc.*, 472 F.Supp. 413 (E.D. Mich. 1979); *Boehringer*

deed, the increased availability of generic substitutes since passage of those laws and the recent expiration of many patents, as pointed out in the Government's Brief Amicus (p. 4, n. 12), may make the problem even more acute now. Defendants Premo Pharmaceutical Laboratories, Inc. ("Premo") and Inwood Laboratories, Inc. ("Inwood") have been parties to other suits in which such practices were involved. Premo has itself sued another manufacturer for selling a prescription drug similar in appearance to Premo's, alleging that, by so doing, that manufacturer would "facilitate, aid and abet in passing off defendant's product as Premo's, thus illegally putting an instrumentality of fraud in the hands of retail pharmacists", *Premo Pharmaceutical Laboratories, Inc.* v. *Zenith Laboratories, Inc.* (D.N.J. Civil Action No. 81-3816, Complaint ¶14).

Inwood's Vice President testified that he knew of the practice of illegal substitution and the defendants admitted that the duplication of the appearance of the innovator product makes such illegal substitution easier. (415A, 405-6A, 438a) Premo's President acknowledged that "it is obvious if a man is going to do something illegal like pass off counterfeit money it's easier if he has a good imitation". (405-6A) A distributor admitted that another of defendants' practices, namely providing listings of brands available from the market leaders juxtaposed with the lists of their look-alike products, also makes it easier for the pharmacist "with larceny in his heart". (228-9a)

Ives proved that in thirteen cases look-alike cyclandelate capsules had been illegally substituted for CYCLOSPASMOL cyclandelate and had been identified on pharmacy labels as CYCLOSPASMOL.[9] (36A, TR 248, 732-81A) In

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Ingelheim G.m.b.H. v. *Pharmadyne Laboratories, Inc.*, 211 U.S. P.Q. 1163 (D.N.J 1981) (hereafter referred to as *Boehringer* v. *Pharmadyne*).

[9] Contrary to the assertion of petitioner Sherry, there was not a "nationwide" shopping, nor were the pharmacists known "bad actors". Some Ives' employees selected pharmacies in various areas

addition, it showed that one pharmacist, packaging cyclandelate for sale to nursing homes, put the look-alike capsules into single dosage unit packs individually labelled CYCLOSPASMOL or CYCLANDELATE CYCLOSPAZMOL (sic). (104-5A, 576A) Subsequent to trial, six indictments were handed down in the Metropolitan New York City area alleging illegal substitution and mislabelling of generic cyclandelate in filling prescriptions for CYCLOSPASMOL. The Court of Appeals, while not assuming guilt of the parties, took judicial notice of these indictments. (PA 84a).

Ives also introduced a statistically projectible survey to show what Judge Friendly had called "intermediate" cases of wrongdoing, namely when substitution is made legally, but the look-alike is then passed off as Ives' CYCLOSPASMOL cyclandelate. This survey, which was conducted in what the Court of Appeals characterized as a "rigorous and impartial manner", showed that 29% of the legally substituted look-alikes were mislabelled by pharmacists as CYCLOSPASMOL.[10] (TR 80-87, Pl. Ex. 82, 354-61A) In addition, in nine of seventeen instances where prescription bottles were produced by patients during survey interviews (infra p. 16), the look-alike capsules were erroneously identified on pharmacy labels as CYCLOSPASMOL. (TR 109-10a, 66-70B, 78-9B, 577-585A) This occurred de-

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of the country which they thought might be making illegal substitutions and prescriptions were presented to determine whether this was so. (36-37A) Inwood now claims for the first time that the substitutions in Michigan were not illegal. They were. The prescriptions were written for CYCLOSPASMOL. Under the law then in effect, even without the direction "dispense as written", it was unlawful to dispense a substitute without first orally advising the consumer. Michigan Public Health Code, §17755(1). Affidavits submitted on the motion for preliminary injunction by witnesses then deposed by defendants, confirm that the required disclosures were not made.

[10] This figure of 29% is correct, not the 12% referred to in the dissent. In computing how many pharmacies mislabel generic cyclandelate as CYCLOSPASMOL, the only true measure is to look to pharmacies that dispensed the generic. Those that did not carry the generic and thus did not substitute at all were properly omitted in computing the percentage of mislabelling.

spite the fact, acknowledged by defendants' expert on pharmacy practice, that pharmacists know the difference between the generic name and the trademark for a drug product. (271A) All manufacturers' bottles from which pharmacists dispense prominently show the generic name. (TR 25a, Pl. Ex. 5, 6, TR 106-7B, Pl. Ex. 39-45)

Thus, thirty-four labels on prescription vials or unit dose packs containing defendants' look-alike cyclandelate showed Ives' trademark CYCLOSPASMOL. Twenty-one showed only CYCLOSPASMOL or the trademark with the generic name, e.g., CYCLOSPASMOL (cyclandelate). (TR 109-112a, 114a, 66B, 70B, 247-248, 392-3, 377; 577-9A, 581-4A, 732A, 736A, 748A, 752A, 756A, 760A, 764A, 770A, 774A, 778A, 781A, 719A, 726A, 723A) On others the trademark was shown with some other designation, as, for example, "CYCLOSPASMOL 400 Cooper", "Rugby CYCLOSPASMOL", or "CYCLOSPASMOL (G)". (TR 247-9, 78B, 82B, 740A, 585A, 576A) Six labels showed "Generic CYCLOSPASMOL" or a variation such as "CYCLOSPASMOL Gen." (TR 392-3, 377; 576A, 699A, 695A, 691A, 703A, 707A) In the New York State shop, in six instances where the generic was dispensed and not labelled with Ives' trademark, the pharmacy label showed no manufacturers' name or other indication of source and, in a Premo shopping, fourteen of twenty-five pharmacists failed to put the manufacturer's or distributor's name on the labels, leaving the capsule color as the only effective indication of source. (Pl. Ex. 82, TR 85, 376A) When, in the Ives' survey, the pharmacist disclosed that a generic had been dispensed, this occurred because the shopper, as part of the survey, was required to ask, after the medication was dispensed, whether it was in fact a generic, and to then record the answer. (TR 81, Pl. Ex. 85)

An examination of prices charged shows a substantial difference from pharmacy to pharmacy. In the New York State survey, for example, the price for the CYCLOSPASMOL 400 mg. dosage ranged from 8.7 to 22.6 cents per capsule. (Pl. Ex. 82G, 820O) Although this practice

was not uniform, there were some substantial windfalls for pharmacists dispensing the generic look-alikes. One pharmacist mislabelling the blue 200 mg. look-alike as CYCLOSPASMOL charged a higher per capsule price than all but one of twenty-three pharmacists who had dispensed the true CYCLOSPASMOL. (TR 392-3, Pl. Ex. 82T, 82Y) One of the pharmacists dispensing the 400 mg. capsules, mislabelled as CYCLOSPASMOL, charged a higher price per capsule than all but two of the 25 pharmacists dispensing 400 mg. CYCLOSPASMOL. (TR 377, Pl. Ex. 82HHH, 82PPP, 82ZZZ) In the Premo shopping, two pharmacies charged more for dispensing cyclandelate than for CYCLOSPASMOL. (379-82A) Once when the look-alike was mislabelled as CYCLOSPASMOL, the "saving" passed on to the consumer was only 55 cents, despite the fact that a 1977 Sherry catalog shows that the pharmacist's own saving on a bottle of 100 cyclandelate capsules, as compared to a comparable bottle of CYCLOSPASMOL, was $6.55. (380A, 624-5A)

A March 13, 1979 Report of Attorney General Robert Abrams and Consumer Affairs Commissioner Bruce Ratner on the New York Generic Drug Substitution Law confirmed that nearly one quarter of the pharmacies in New York violate the generic drug law when filling prescriptions and that they are not passing along the full dollar savings to consumers. The report also verifies that the retail price charged by some pharmacies for the generic substitute is often significantly higher than the retail price charged by other pharmacists for the branded product. And, the Report concludes, the State Pharmacy Board has given prosecution of violations of the New York generic drug law a low priority. (TR 933, 368-74A)

C. *The Functionality Issue*

When chosen by Ives, the blue and blue/red colors were completely arbitrary. They do not contribute to the therapy offered by cyclandelate, which is a white powder, and they are not medically necessary. Many thousands of other color

combinations could have been selected by defendants for the capsules, and they could even have chosen to sell the drug in tablet form. (TR 24a, Pl. Ex. 3) One competitor, W.E. Hauck, Inc., has sold cyclandelate in an all red 200 mg. capsule for at least two years. (124-5A, Pl. Ex. 19, 729A) Its product is shown on the Georgia Medical Assistance Drug List and in the Consumer Guide publication on prescription drugs as a generic cyclandelate available to patients. (TR 80a, 82a, 15, 573-5A, 730A)

Other manufacturers do not feel similarly compelled to copy the innovator. Information in the Physicians Desk Reference alone shows that, in numerous instances, the same drugs in the same dosage forms, but in different colors, are available and color change will occur in medications for both acute and long term therapy and even for treating anxiety (169-71A, 185-6A, 109A, 110-11A, Pl. Ex. 131-135). For example, the most widely prescribed vasodilator, papaverine hydrochloride, comes from different sources in the same dosage but in seven completely different color combinations. (TR 937-939, Pl. Ex. 131) No proof was offered that patients would not equally accept other color choices for capsules containing cyclandelate.[11]

Several expert witnesses testified. Dr. Heinz Lehmann, one of the world's foremost psychiatrists, and a member of the Research Advisory Committee to the New York State Department of Mental Health, who has treated over 10,000 patients, testified that it is not medically necessary for the same dosage form of the same prescription drug to be of the same color. He had treated patients whose drug colors were changed and encountered no refusals to take the medication, no anxiety reaction on the part of the patients, and no indication that the therapeutic effect was diminished by the color change. (191-4A) Dr. Eric

[11] Defendants' Dr. Stempel testified that look-alike generics had been marketed for years, and provided a chart of look-alikes, but he did not know whether any of them were presently marketed. Twenty-eight were round white or off-white tablets. Several were the subject of pending litigation. Thirty-seven were also available in non-look-alike forms. (265-6A, 304A)

Fine of the Albert Einstein Medical Center in Philadelphia, and Dr. Vincent Desiderio, Medical Director of the Sidney Hillman Medical Center, related similar experiences. (109-13A, 311-14A,) All three physicians testifying for defendants also acknowledged that generics which did not copy the appearance of innovator drugs were available, and that their patients had from time to time received medication in colors different from those previously dispensed without unfavorable reaction. (219A, 299-301A, 257-8A) One of defendants' witnesses, Dr. Taylor, admitted that her personal view that all drugs with the same ingredient should be the same color was not a reflection of what actually exists in the market place. (219A) All three of defendants' physicians testified that, where their patients inquired about color change, it was explained to the patient's satisfaction, except for one patient with cardiac problems and a few with Parkinson's disease who did not want to switch the source of their medication. (255-8A, 296A, 299-301A, 250A, 255A, 210A) The total of six physicians who testified about their experience with color change represented collectively over 125 years of medical practice, and had treated tens of thousands of patients, yet these are the only examples of patient refusal any could remember.

Reliance on color as an identification of a kind of medication can be dangerous. The practice of commingling medication in one container, and selecting from that collection by color, was universally condemned particularly since a single patient could be taking medications which are different, but which come in capsules or tablets of a very nearly identical appearance. (115A, 231-2A, 253A, 261A) Defendants' Dr. Bloom acknowledged that a patient relying on color to select one type of medication over another in those circumstances could be in trouble. 261A) The safest and most sure way of identification for professionals is a drug's National Drug Code identifying number, not its color. A specialist in emergency medicine testified that a responsible physician would not at-

tempt to make a positive identification of an overdosed drug by color alone and that such reliance could be disastrously harmful. (196-7A) The Drug Abuse Manual for Law Enforcement Officers, which notes that some over-the-counter products may look like amphetamines or barbituates, counsels that "simple visual inspection cannot be relied upon for drug identification". (197A, Pl. Ex. 114) Defendants' witness Dr. Stempel, a pharmacy expert, confirmed the dangers in relying on color (TR 807, 365A):

> "Any attempt to identify a drug wholly by its physical characteristics, aside from being time-consuming, can be hazardous, and this procedure should be discouraged . . . even though one life may be saved by identification by appearance, encouraging such a procedure may lead to other lives being lost."

Uncontradicted evidence as to pharmacy practice was submitted. Pharmacists, including the President of the Pharmaceutical Society of the State of New York, testified that the same drugs in the same dosage form but in different colors are and have been widely available and used, and that they had not encountered patient refusal of a drug because of a color change. (170-2A, 183-8A) The Nassau County Medical Center has often changed the supplier of its drugs, and thus their color, and encountered no resistance to color change from patients, doctors, or nurses. (187-8A) If a change in color results in a patient inquiry, an explanation by the pharmacist or physician is sufficient and there is no evidence that professionally responsible physicians or pharmacists would be unwilling to take the time to explain the change. (172A, 188A) Defendants' pharmacist witnesses likewise acknowledged that color change has occurred in their practice, and that they stock generics in colors different from the market leader. (276A, 242-6A)

The entire testimony about industry resistance to non-look-alikes was as follows. A pharmacist testified that he

preferred not to purchase cyclandelates in green capsules, a color once offered by an affiliate of Inwood. However, his reason was concern about a problem he had when, because of a color change, two *entirely different* medications looked similar. (276-7A, 280-1A) An officer of Inwood testified that someone told him that one or two hospitals complained about the product sold in green capsules, but he could not identify them or furnish details about the complaint. (418A, Pl. Ex. 144 pp. 85-6) Finally, a wholesaler testified that he preferred to sell look-alikes. He was an employee of a defendant in a case then pending in which such practices were challenged, and subsequently enjoined. (TR 669, *A.H. Robins* v. *Medicine Chest*, supra p. 7 n.8)

Additional uncontradicted and significant testimony related to the actual purchasing practices of hospitals and similar institutions including the New York City Health and Hospitals Corporation, the Nassau County Medical Center, the Sidney Hillman Medical Center and others. Without exception, purchasing decisions at such institutions are *required* to be made on price, not color. (184A, 215A, 241-3A, 301-2A) Such institutions frequently change their source of supply and, in many instances, this results in a color change. (183-6A, 243A, 283A) Local, state and federal bidding specifications for cyclandelate throughout the country, including those of the Veterans' Administration, include no reference to color.[12] (315-17A)

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[12] The only exception is New Jersey's bidding form for 200 mg. cyclandelate which refers to the color blue. It does not, contrary to the statement in Inwood's brief, have a color requirement for the 400 mg. dosage form. Since New Jersey purchases other products regardless of color, it is probable that the State would also remove that requirement were a bid received for 200 mg. cyclandelate sold in capsules other than blue. There was no evidence proffered by defendants that they ever attempted to make such a bid (316A, 318A)

D. *Confusion and the Significance of Color*

Ives also introduced a survey in support of its claim that duplication of the capsule colors causes confusion, since the colors are associated with CYCLOSPASMOL. There was extensive testimony about the procedures used to design, execute, and validate the results of this survey.[13] (131-4A, 151-3A, 158-9A, 165-7A, TR 69, 77, 319A, 347A, 352A) Seventy-one patients were interviewed (not thirty-six as stated by the District Court), forty-three in an initial survey, and twenty-eight in a replication survey. (319A, 347A, 352A) Three pharmacy bottles containing defendants' look-alike capsules were displayed to each patient. The bottles were all correctly labelled with the name of the manufacturer or distributor, and the generic name of the product, cyclandelate. Premo's capsules bore the imprint Premo. (141A, Pl. Ex. 80a-c) Nonetheless, the combined misidentification by patients of look-alike blue and blue/red capsules as CYCLOSPASMOL in the original survey was 70%, with 40% making a spontaneous misidentification.[14] (TR 69, 319A, 323A, 347A, 350A) Were one to discount patients who were not even aware that CYCLOSPASMOL had ever been prescribed for them, the total misidentification increased to 97%, with 57% making a spontaneous misidentification. The replication patient survey showed similar results. (TR 77, 352A) 79% of the patients in the original survey said they used color to make their identification of what they erroneously believed to be CYCLOSPASMOL. (TR 72, 319A, 325A, 347A)

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[13] The District Court made no findings on the methodology or survey techniques used, but gave the survey little weight. The Court of Appeals decision does not mention the survey. It will not be extensively discussed here since it relates principally to Ives' 43a claim, which, not having been decided below, is technically not before this Court.

[14] A spontaneous misidentification is one in which the person interviewed identified the look-alike capsules as CYCLOSPASMOL upon seeing the capsules, without first having been shown a list of ten drug names.

III.

The Decisions After Trial

The District Court again rejected plaintiff's claims. On the contributory infringement claim, it apparently did not believe that furnishing the look-alike capsules could itself result in liability. Rather it looked only at defendants' promotional material and believed that it could not "fairly be read as suggesting to druggists that they affix Ives' mark to bottles containing defendant's capsules". (PA 59a) It also speculated that the pharmacists who mislabelled the look-alikes as CYCLOSPASMOL (none of whom were deposed or called by defendants as witnesses) must have misunderstood the requirements of the New York Drug Substitution Law. (PA 60a) The Court considered requiring defendants to affix labels on bottles sold to pharmacies warning against illegal substitution or misbranding, or requiring defendants to imprint some identification on their capsules, but rejected both forms of relief as ineffective. (PA 61a) It thus gave no relief at all.

As to the claim under §43a, it held that the colors of the capsules were functional. (PA 63a) In so doing, it did not explain why cyclandelate differed from the numerous generic drugs sold in non-look-alike forms. It also held that Ives had failed to prove secondary meaning, despite evidence of extensive sales and promotion. Although patients in a survey had identified the defendants' look-alike capsules as CYCLOSPASMOL, the Court held that plaintiff had not also proved that they thought CYCLOSPASMOL was a trademark. Indeed, it found without benefit of testimony from a single patient, or other evidence, that to them the word refers to an ingredient. (PA 67a)

The Court assumed that relief under state law was not precluded by *Sears/Compco*, but held that the "interest of the patients must be weighed against the policy expressed in the New York Education Law to encourage legal sub-

stitution of lower priced drugs". (PA 69a). Although a change in capsule color might deter a wrongdoer, the Court believed it would also inhibit legal substitution, and denied relief under this cause of action as well. (PA 69a)

The Court of Appeals reversed the decision of the District Court. Although it did not decide the §43a or state unfair competition claims, it did specifically reject the holding that the colors were functional, stating that defendants "have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically-colored, look-alike cyclandelate capsules instead of capsules of a different color, size or shape, which would minimize the practice of mislabelling, illegal substitution or confusion". (PA 84a) It specifically found "unconvincing" the assertions that capsule colors are functional and should be copied because the look-alikes reduce patient confusion or anxiety, enable doctors to communicate with patients more easily concerning their medication, and aid in identification in emergencies. (PA 84-85a) The Court also emphasized that there was no evidence that patients would be confused by receiving a non-look-alike, or that a color change could not easily be explained. (PA 85a)

On the contributory infringement claim, which is the subject of this appeal, the Court held that, by furnishing the look-alike capsules, defendants were liable when pharmacists misidentified them with plaintiff's trademark on pharmacy vials containing those look-alike capsules. It acknowledged that "it was surprising that Ives was able to produce as many instances" of illegal substitution as it did, and that Ives' pharmacy shop, done in a "rigorous, impartial manner", disclosed substantial evidence of intermediate cases of contributory infringement, i.e., mislabelling of legally substituted look-alikes. (PA 81a) This evidence, the Court held, was clearly sufficient to establish a violation of §32 of the Lanham Act, since the manufacturers could reasonably anticipate that their look-alike product would be substituted illegally or mislabelled by a substantial number

of druggists. (PA 82a) The fact that the capsules were look-alikes reduced the likelihood of detection by patients.

The Court also noted that the record did not justify the finding that the mislabelling occurred as a result of confusion by pharmacists, and that, in fact, it was the District Court judge himself who suggested this, in a casual exchange with one of the witnesses. (PA 83a)

The Court did suggest that listing the comparative prices of CYCLOSPASMOL and generic cyclandelate may have furnished an added inducement to pharmacists, when combined with the furnishing of look-alike capsules and catalogs describing their appearance. However, the relief given was an injunction against the sale of the blue and blue/red look-alikes; there were no restrictions suggested, and none imposed by the District Court on remand, on accurate price comparison or other truthful advertising of the defendants' product. (PA 102-4a)

Summary of Argument

Ives does not seek to prevent the sale of generic cyclandelate. It does not seek to restrict truthful comparative advertising by manufacturers of generic cyclandelate. It does ask this Court to affirm a decision imposing on the defendants the obligation to compete fairly and, specifically, not to sell their cyclandelate drug in capsules that imitate the appearance of the blue and blue/red capsules in which Ives' CYCLOSPASMOL brand of cyclandelate has long been sold.

The Court of Appeals correctly held that, by furnishing these look-alike capsules to pharmacists who illegally substituted and otherwise passed them off as Ives' CYCLOSPASMOL capsules, the defendants were liable for contributory infringement under §32 of the Lanham Act, 15 U.S.C. §1114. The acts of those pharmacists were clearly an infringement of the CYCLOSPASMOL trademark. Its validity was never challenged, and no evidence was ever

submitted that it functioned as anything but a trademark. To affix that mark to products emanating from a source other than Ives obviously violates §32.

To hold the defendants vicariously liable for that infringement by pharmacists is completely consistent with well-established principles of tort law holding persons liable for the reasonably foreseeable consequences of their actions. Pharmacists, as the direct link to the consumer, play an integral and unique role in the marketing of prescription drugs. It has historically been known that they do not always behave in a responsible, professional manner. When, in this and numerous other cases, they have been presented with prescription drugs mimicking the appearance of the innovator, and further tempted by the increased profits possible, pharmacists have illegally substituted or otherwise passed off the look-alikes for the branded products of the innovators. In this case, defendants admit that their duplication of the capsule colors made the pharmacists' acts of passing off more likely to occur, and less easy to detect.

Color duplication results in the deception of those patients who receive look-alikes when their physician has directed that only the branded product be dispensed. The similarity in appearance makes it unlikely that any patient would discover the ruse. The look-alikes also do a disservice to patients whose physicians have authorized generic substitution. Seeing the familiar colors, they will not be alerted to the fact that substitution has occurred, and will not know that they should require the pharmacist to pass along some saving to them.

To deny liability in these circumstances would represent an unwarranted and unwise departure from well-established law and, in particular, well-established case law setting standards applicable to the unique circumstances that exist in the marketing of prescription drug products. And, absent some compelling reason for allowing defendants to continue to provide the instrumentality of fraud to the

pharmacists, the Court was also completely correct in fashioning as the only effective relief an injunction against copying the appearance of Ives' capsules.

The defendants failed completely to furnish any legitimate reason for copying the appearance of the Ives' capsules let alone one so compelling as to justify the continued sale of a product that has been the instrument of fraud and deception of the consumer. In this as in other cases defendants have claimed that the colors are functional, and thus free for all to copy. Their argument rests on the premise that patients will refuse a color change, and that, by selling the look-alikes, they avoid that refusal by concealing the change.

Other manufacturers, however, sell drugs having the same therapeutic indication and ingredients as the market leader, but do not copy the appearance of the tablets or capsules in which that product has been sold. No legitimate reason was given why the defendants should not also follow that practice. The claim that a color change would lead to a decreased availability of generic drugs, or a rise in their cost, has never been supported by probative evidence. The Court correctly held, as have other Courts addressing the issue, that there was a failure of proof by defendants.

Requiring that cyclandelate be sold in capsules that do not copy the Ives' capsules is completely consistent with the policy, as embodied in the *Sears/Compco* cases, of allowing the copying of the subject matter of patents after expiration. Defendants are free to copy the *product*, i.e., cyclandelate, but not the trade dress in which the product has been sold by Ives.

To enjoin the copying of the blue and blue/red capsule colors is not, as the Department of Justice suggests, to err on the side of overdeterrence. The benefits to be gained by requiring a change in color are not marginal. They are extremely important. They include not only the interest of the plaintiff in assuring that the drug products

of others are not passed off as plaintiff's, but also the interest of the public in being able to determine that the correct drug has been dispensed, and the correct price charged. They assure that the patient is not deprived of the right to exercise informed consent as to the source of his or her medication. These interests far outweigh any cognizable interest the defendants may have in continuing their copying. There is no proof in this record that their ability to compete fairly in the sale of cyclandelate will be diminished were the colors changed.

ARGUMENT

I.

The Court of Appeals Was Correct in Holding That the Defendants, by Furnishing Cyclandelate in Capsules Imitating the Appearance of Ives' Cyclospasmol Capsules, Were Guilty of Contributory Infringement When Those Capsules Were Passed Off as Cyclospasmol.

A. *The Legal Criteria Applied Were Correct and Liability Was Factually Established*

We have, with prescription drugs, a unique marketing situation in which a third party, the pharmacist, not only plays an integral role, but, in fact, actually labels the merchandise as dispensed to the ultimate consumer. Respondent does not claim that all or most pharmacists cut corners, or attempt to deceive consumers and increase their profits by illegally dispensing or mislabelling the defendants' product. However, historically, such activity has been a serious problem for the innovator, and for the consuming public. In the 1950's, for example, the manufacture of look-alike drugs had reached epidemic proportions, and pharmacists were making illegal substitutions 25% of the time. (FTC Report, *supra*, p. 7) Evidence submitted in other recent cases shows that the practice continues (*supra*,

p. 7 n.8) Although difficult to discover, since patients do not realize there has been illegal substitution of a look-alike, and thus do not report it, Ives nonetheless showed numerous instances of illegal substitution of cyclandelate. It also showed that the product is passed off by pharmacists as CYCLOSPASMOL 29% of the time when the look-alike is legally dispensed. (*supra*, p. 9)

The widespread existence of passing off and illegal substitution over the years has spawned many law suits which establish and delineate the liability of those, such as the defendants herein, providing look-alike drugs.

In *William R. Warner & Company* v. *Eli Lilly & Company*, 265 U.S. 526 (1924), this Court acknowledged the vicarious liability of the manufacturer of a liquid quinine preparation, which was passed off as the product of the pioneer. It rejected the argument that liability does not lie because the manufacturer, at its point of sale, does not deceive its customers. The fact that those customers, the pharmacists, were not deceived, but "knew exactly what they were getting is of no consequence". (p. 530) The wrong, the Court held, "was in designedly enabling the dealers to palm off the preparation as that of the respondent". (p. 530) The question of liability in that case seems one which not even the defendants herein would challenge, since the manufacturers' salesmen had suggested to pharmacists that, without danger of detection, prescriptions and orders for the products of the market leader could be filled by substituting the copy. By also pointing out the enhanced profit to be made, they further actively induced the substitution which, at that time, was illegal.

The *Lilly* case was only a first step, and clearly does not set the far limits of liability. Subsequent decisions hold that a manufacturer cannot escape liability merely because it does not employ salesmen who actively induce or participate in the passing off. *Smith Kline & French Laboratories* v. *Heart Pharmaceutical Corp.*, *supra*, p. 7 n.7,

presents a typical marketing scheme which historically has triggered liability (90 F.Supp. at p. 978):

> "[T]he affidavits submitted do not allege any direct instance in which defendants or their agents suggested to druggists that their product might be substituted for that of plaintiff without danger of detection. However, this court cannot be insensible to the practical effect of defendants' advertisements and the use of the term 'Color Guaranteed'. Certainly the possibility of substitution was brought to the mind of druggists by the pictorial representation of the shape and the designation of the colors of defendants' tablets as well as the lower prices at which they could be obtained."

The Court in *Smith Kline & French Laboratories* v. *Broder, supra,* p. 7 n.7 also acknowledged the existence of illegal activities by pharmacists and held the manufacturers liable for contributing to them (125 U.S.P.Q. at p. 302):

> "Substitution by retail druggists of another drug, or the product of another manufacturer, than that called for by the physician's prescription, is an unethical practice in the drug business, and is criminal in this State [Texas], as well as many others. It is, however, practiced *in many instances,* there being a financial inducement thereto, in that the imitative drug usually sells for a fraction of the price which the genuine and well advertised product commands." (emphasis supplied)

The defendant in that case had duplicated the shapes and colors of the plaintiff's products, and emphasized these similarities in circulars distributed to retail pharmacists. The Court held that "the obvious purpose and effect of defendant's said advertising is to suggest that the druggist can readily substitute defendant's imitation drug products in filling physicians' prescriptions calling for plaintiff's trademarked products" and found the manufacturer liable.

These standards for holding the manufacturer liable have not been relaxed with the advent of generic substitution laws which provide that substitution, when authorized, is legal. It has been held, for example, that New York's generic drug substitution law "does not promote unfair competition or the infringement of drug patents and trademarks; nor does the Law create any defenses to such claims . . . plaintiffs' rights and remedies under the patent and trademark laws are the same now as they were prior to the passage of the law," *Pharmaceutical Manufacturers Association, et al.* v. *Whalen* (New York Court of Appeals, No. 650, December 22, 1981, Slip Op. p. 7). The problem of illegal substitution, and misbranding, is still very real. Its exact magnitude cannot be known because the acts complained of are clandestine, and not discovered by patients who cannot tell they have been deceived.

Although other recent cases were decided under §43a of the Lanham Act and various state laws of unfair competition, rather than §32 of the Lanham Act, they are nonetheless directly pertinent insofar as they recognize the unique distribution pattern and the resulting standard of accountability still applicable in the prescription drug industry. In *A. H. Robins* v. *Medicine Chest, supra,* p. 7 n.7, defendants were enjoined from selling a generic drug in look-alike blue tablets. The Court applied this general standard in finding Inwood and other defendants liable (206 U.S.P.Q. at p. 1019):

> "Anyone who puts goods into the hands of dealers for sale to the public which contain the means for deceiving purchasers, and/or which can be reasonably anticipated to so deceive, is subject to an injunction against the further provision of these means . . . Thus defendants . . . can be held liable for putting their products into various dealers' hands, such as defendant-pharmacists, *if they can reasonably anticipate that their goods may be passed off as goods of another, whether or not they conspired with the dealer or*

intend the substitution of the goods involved." (emphasis supplied)

Similarly, the Court of Appeals for the Third Circuit, in *SK&F* v. *Premo, supra,* p. 6 n.4, found that the defendant's conduct was actionable since it put a look-alike prescription drug capsule "in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product *even if the manufacturer does nothing else to encourage passing off.*" (625 F.2d at p. 1062, emphasis supplied) In *Boehringer* v. *Pharmadyne, supra,* p. 8 n.8, it was also held that, by copying plaintiff's orange colored tablets, the defendants "made possible the 'switching' of consumers for the profit of pharmacists," and indeed "provided the essential ingredient for that practice." (211 U.S.P.Q. at p. 1183) In *Hoffmann La Roche* v. *Premo, supra,* p. 6 n.4 liability was similarly determined on a realistic basis (210 U.S.P.Q. at p. 383):

> "When a manufacturer produces articles that copy the trade dress of another and puts them in the channels of trade, then though he sells only to wholesalers or distributors he cannot realistically be heard to say that he is unaware or ignorant of what retailers may do by way of 'passing off' or 'palming off' his goods as those of another."

The criteria applied in this long-established line of other prescription drug cases, and in this case, are but applications of the basic principle of tort law holding one liable for the reasonably foreseeable consequences of his or her actions. The concept is firmly established in our jurisprudence, specifically in other unfair competition cases, which hold that "it is unfair competition for a person to put a product into a dealer's hands which a producer can reasonably anticipate may be easily passed off as the goods of another," *Union Carbide Corp.* v. *Ever-Ready, Inc.,* 531 F.2d 366, 384 (7 Cir. 1976), *cert. denied,* 429 U.S.

830 (1976); *Corning Glass Works* v. *Jeannette Glass Co.*, 308 F.Supp. 1321, 1326-28 (S.D.N.Y. 1970), aff'd on opinion below, 432 F.2d 784 (2 Cir. 1970); *Andrew Jergens Co.* v. *Bonded Products Corp.*, 21 F.2d 419, 424 (2 Cir. 1927), *cert. denied*, 275 U.S. 572 (1928); and *Stewart Paint Mfg. Co.* v. *United Hardware Distributing Co.*, 253 F.2d 568, 575 (8 Cir. 1958); see also R. Callmann, The Law of Unfair Competition Trademarks and Monopolies, §87.2(b)(1) (3d ed. 1970). To absolve the defendants in this case would represent a severe inroad on this well-established body of law.

The contributory infringement concept is a salutary one. Ives did sue one druggist who had illegally substituted and misbranded look-alike cyclandelate capsules. He admitted liability and consented to an injunction. (29-31A) However, there are over 3,000 pharmacies in New York State alone. (TR 80) The purpose of the contributory infringement concept is both to avoid the multiplicity of suits resulting were one required to sue even a small proportion of those many retailers, and also to have the person providing the means for deception shoulder the responsibility. Where the issue is whether patients are receiving a prescription drug from the source specified by their physicians such relief is imperative.

The Government suggests that the Court should have applied a stricter rule of scienter and Inwood would require that Ives prove that it continued to sell to specific, identified pharmacies engaging in the acts complained of. These approaches are naive. The defendants did not accidentally select the colors blue and blue/red for their cyclandelate capsules. They selected them only because CYCLOSPASMOL capsules were blue and blue/red. The excuses they fashioned for copying were held to be "unconvincing" and "not persuasive." (PA 84) The defendants also knew that they were releasing into the stream of commerce an instrumentality for fostering deception. They have admitted that duplication of the capsule ap-

pearance makes illegal substitution and misbranding by the pharmacist more likely, and less easily detectable by the patient. Such misbehavior by pharmacists has unfortunately long been a known fact of life and defendants cannot plead ignorance of this practice in the drug trade. In fact Inwood admitted to knowing of the practice. Defendants have a special obligation not to contribute to this wrongdoing, particularly given the fact that the product involved is a prescription drug. Instead, they made it easier by providing look-alikes, and encouraged the wrongdoing further by noting the color identity in catalogs, and matching their products in columns with the trademarks of Ives and other innovators.[15]

This entire body of law establishing the liability of drug manufacturers is solidly based on the realities of the prescription drug business and conforms to established standards of accountability in tort law. It should not be disturbed except for the most compelling reasons, which clearly have not been shown on this record.

B. *There Was Direct Infringement by Pharmacists of the CYCLOSPASMOL Trademark*

Inwood argues that the Court erred in finding contributory infringement because it had not first specifically held that the direct wrongdoers, the pharmacists, had infringed Ives' trademark. Since those pharmacists applied Ives' CYCLOSPASMOL trademark to products that were not Ives' CYCLOSPASMOL cyclandelate, the argument must be characterized as specious.[16]

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[15] *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, supra p. 3 is distinguishable. It is common knowledge that some physicians require that their patients receive exactly the branded drug prescribed; as aforesaid, the existence of the look-alikes interferes with that choice. The Court specifically noted, however, that there was no evidence in *Snow Crest* that customers wanting a cola drink made specific orders by brand name or that furnishing a substitute would interfere with their choice. (64 F. Supp. at p. 988).

[16] While less blatant an infringement, this is true even of those vials labelled CYCLOSPASMOL Gen, or CYCLOSPASMOL

It does, however, lead to another argument made by Inwood, and echoed by defendants' trade association, namely that CYCLOSPASMOL is not a trademark, but merely signifies the ingredients in the drug. This hypothesis was first interjected into this case by the District Court after trial when it held that "such patients as read their prescriptions do not attribute to Cyclospasmol 'any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue.' " (PA 67a) The quotation is not from any evidence in this case, but is, verbatim, a finding in a case involving a challenge to the trademark status of "aspirin." In that case there was substantial evidence that "aspirin" had been used descriptively even by the plaintiff, which promoted its product as "BAYER Tablets of Aspirin," and had thus become recognized as a generic name, *Bayer Co.* v. *United Drug Co.*, 272 Fed. 505, 510 (S.D.N.Y. 1921).

In the present case, however, defendants did not question the trademark status of CYCLOSPASMOL, and stipulated that it is a valid, subsisting, incontestable registered trademark. (34A) Ives is entitled to a statutory presumption of validity, and the District Court clearly erred in presuming invalidity of the trademark and its registration and suggesting that Ives had the burden to prove its trademark was a trademark, 15 U.S.C. § 1115a. Even had the defendants raised the issue of validity at trial and introduced evidence to support the claim, (which they did not) the cases clearly establish that defendants would have the burden to prove by "a rather clear and convincing showing" that CYCLOSPASMOL was *not* a trademark, *E. I. duPont de Nemours & Co.* v. *Yoshida International, Inc.*, 393 F.Supp. 502, 528 (E.D.N.Y. 1975); *McGregor-Doniger Inc.* v. *Drizzle, Inc.*, 599 F.2d 1126, 1132 (2 Cir.

Generic. As the Court pointed out in *Boehringer* v. *Pharmadyne, supra*, p. 8 n.8, "whether adding the letters 'gen' or the word 'generic' actually tells the consumer that he or she is being switched from Persantine is questionable . . . Consumers are unlikely to learn of the change in medication from what is probably, for them, an obscure word or phrase." (211 U.S.P.Q. at p. 1181.)

1979); *Marks* v. *Polaroid Corp.*, 129 F.Supp. 243 (D. Mass. 1955) aff'd 237 F.2d 428 (1 Cir. 1956), *cert. denied*, 352 U.S. 1005 (1957).

It has also been suggested, again belatedly, that, when the patent on the active ingredient in cyclandelate expired, competitors were free not only to make the product, but also to use the CYCLOSPASMOL trademark. There is, however, no rule of law that its trademark follows a product into the public domain upon patent expiration. There is not even a presumption that the name becomes *publici juris*, Handler and Pickett, Trade-Marks and Trade Names —An Analysis and Synthesis: I, 30 Columbia Law Review 168, 187 (1930). In each case, facts establishing the genericness of the one-time trademark must be proved, *Telechron, Inc.* v. *Telicon Corp.*, 97 F.Supp. 131, 151-52 (D. Del. 1951) aff'd 198 F.2d 903 (3 Cir. 1952). *Singer Manufacturing Co.* v. *June Manufacturing Co.*, 163 U.S. 169 (1896), cited as authority in this attack on the validity of CYCLOSPASMOL, is clearly distinguishable. In *Singer*, as in the *Bayer* case, *supra*, p. 29, there was proof that the purported trademark had in fact been used as, and was understood to be the name of, a certain type of machine. *Saxlehner* v. *Wagner*, 216 U.S. 375 (1910), also cited, likewise does not support defendants' claim, for in that case the name in question had significance only as a geographical expression. In the present case, there is no evidence that CYCLOSPASMOL, as opposed to the term cyclandelate, ever functioned to identify any ingredient or therapy either before or after patent expiration.[17]

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[17] Parenthetically, the evidence reinforces the legal presumption that CYCLOSPASMOL functions as a trademark. A patient in the replication survey, for example, misidentified the defendants' blue/red capsules as CYCLOSPASMOL, but added the comment "But we take the generic one and it's called Cyclandelate and dr. said it's the same and it costs a lot less". (TR 76, Pl. Ex. 78) In New York, the law requires that prescription labels showing a generic name also include the name of its source; that is not required when the trademark is used on labels, the presumption, as

The question of secondary meaning of the appearance of the Ives' capsules may be relevant to the claim under §43a of the Lanham Act, but not to the claim under §32, *Vibrant Sales, Inc.* v. *New Body Boutique, Inc.*, 211 U.S.P.Q. 297, 301 (2 Cir. 1981). The issue under §32 is not whether the appearance of the capsules is itself a trademark, or whether use of the colors on the products of defendants constitutes a false representation or a false designation of origin. The issue is whether the defendants, by furnishing the instrument making infringement possible and more likely, should be liable for the unquestioned infringement of Ives' registered trademark CYCLOSPASMOL when that trademark is used on pharmacy labels to identify the defendants' products. "Protection is accorded against unfair dealing whether there is a technical trademark or not." *William R. Warner Co.* v. *Eli Lilly Co.*, *supra*, p. 23 (265 U.S. at p. 531) Thus, an oral communication to pharmacists suggesting the passing off is actionable and will obviously be enjoined. By making the communication herein, i.e., furnishing the look-alike capsules (and further emphasizing the colors in their catalogs),[18] defendants are equally liable because of the reasonable foreseeability of the pharmacsts' misbehavior. The activity to be enjoined, i.e., the furnishing of look-alikes, is a crucial element in the behavior which leads to deception of the consumer, *Pro-Phy-Lac-Tic Brush Co.* v. *Abraham & Straus, Inc.*, 11 F.Supp. 660 (E.D.N.Y. 1935); *H. A. Metz Laboratories* v. *Blackman*, 153 Misc. 171, 179, 275 N.Y. Supp. 407 (Sup. Ct. N.Y. County 1934).

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admitted by defendant's Dr. Stempel, being that, by itself, the drug's trademark serves as an indication of source. "Obviously everyone knows [the trademark] is the ownership of the specific company . . ." (TR 784)

[18] Defendants represent that it has long been a practice for generic manufacturers to duplicate the appearance of innovator products. They have never explained why, if this is true, it was necessary for the defendants to emphasize the color identity in their promotional material.

For the same reason, cases cited by various petitioners suggesting that color per se does not function as a trademark are not relevant. Ives does not claim that it alone in the pharmaceutical industry has the right to sell drugs in blue or blue/red capsules. The relief sought and granted enjoins only the sale of *cyclandelate* in such capsules because the identity of color in that instance leads to illegal substitution, passing off, and deception.

Nor can liability be escaped merely because the physician chooses the product, but the patient purchases and consumes it, *E.R. Squibb & Sons* v. *Premo Pharmaceutical Laboratories, Inc., supra,* p. 6 n.5 (195 U.S.P.Q. at p. 549). To hold otherwise would mean that consumers of prescription drugs would have *less* protection than would consumers of ordinary products, a result directly contrary to what Ives suggests are the correct cases, holding that such consumers are entitled to even *more* protection, given the special nature of prescription drugs, *Syntex Laboratories, Inc.* v. *Norwich Pharmacal Co.*, 437 F.2d 566 (2 Cir. 1971).

II.

Enjoining the Copying of the Capsule Colors Is the Only Relief That Can Effectively Prevent Further Deception, in Support of the Policies Embodied in the Lanham Act, and Is Completely Consistent With Federal Policy Encouraging Competition and with State Substitution Laws.

A. *The Relief Granted Was Appropriate, and Necessary to Avoid Further Deception*

Judge Mansfield held that the simplest way to reduce illegal substitution and mislabeling is to require that cyclandelate be sold in capsules that do not resemble those used for CYCLOSPASMOL. This would alert patients to the possibility that they have been given cyclandelate when their doctor specifically prescribed CYCLOSPAS-

MOL, as well as put them on notice that the lower cost of generic cyclandelate should have been charged if that is what they received. (PA 86a) Although the various petitioners and amici urge that the Court should have fashioned relief that did not require color change, they do not agree on what should have been done. None of the lesser forms of relief suggested are realistic and none give adequate protection to plaintiff or the consumer.

The New York Attorney General urges that the imprinting of a symbol on the otherwise identical capsules would sufficiently disclose their source to patients. This product is taken principally by the elderly, whose eyesight may be failing, and any imprint must perforce be very small. The District Court acknowledged that, realistically, such an imprint would "be of little if any value". (PA 61a) The Court in *SK&F* v. *Premo, supra,* p. 6 n.4, also noted, after examining a small maroon and white capsule, that "to our over-fifty eyes the logos are decipherable only with great difficulty". (625 F.2d at p. 1061) Where the proposed imprint is a number, as, for example, Inwood's "258," it is evident that, even were it visible, it could not effectively serve as a distinguishing characteristic for laymen.[19]

The second remedy, suggested by Premo, is to require that a label warning them not to illegally substitute or mislabel be put on bottles sold to pharmacists. Such relief was granted in *William R. Warner & Co.* v. *Eli Lilly & Co., supra,* p. 23, where duplication of the product's brown color could not reasonably be enjoined because the color, unlike the present case, was dictated by the necessary chocolate ingredient and was thus functional. In *Upjohn Co.* v. *Schwartz,* 246 F.2d 254 (2 Cir. 1957) similar limited relief was granted for the same reason. Even in those circumstances, where the more effective relief was unavail-

[19] In the survey, patients identified even the blue and blue/red capsules imprinted with the name Premo as CYCLOSPASMOL. Capsules imprinted with the name Premo were passed off by one pharmacist as CYCLOSPASMOL. (TR 87, 726A)

able because of the nature of the particular products, the *Lilly* relief has been strongly criticized by a leading authority as granting protection that "was quite inadequate and invited the substitution which it sought to prevent," W. J. Derenberg, Trade-Mark Protection and Unfair Trading, 264 (1936). Recent cases agree that disclaimers are not a reasonably effective way of preventing confusion, even in those instances where the ultimate consumer sees the disclaimer, see e.g. *Boston Professional Hockey Association, Inc.* v. *Dallas Cap & Emblem Mfg. Inc.*, 510 F.2d 1004, 1013 (5 Cir. 1975), *cert. denied*, 423 U.S. 868 (1975). Here the customer/patient would not see the disclaimer, which would appear only on the manufacturers' bottles as sold to the pharmacist. So, once again, the responsibility for compliance would rest on the pharmacists. If they do not obey the requirements of the law, it is unrealistic to assume they would obey the manufacturers' warning label. Thus the District Court held that such statements are hardly likely to deter deliberate and fraudulent substitution. (PA 61a) This Court's comments in *Virginia State Board of Pharmacy* v. *Virginia Consumer Council, Inc.*, 425 U.S. 748, 769 (1976), apply equally here:

> "There is no claim that the advertising ban in any way prevents the cutting of corners by the pharmacist who is so inclined. *That pharmacist is likely to cut corners in any event.* The only effect the advertising ban has on him is to insulate him from price competition and to open the way for him to make a substantial, and perhaps even excessive, profit in addition to providing an inferior service." (emphasis supplied)

The Government suggests a third form of relief,[39] which has not previously been considered by any Court, or suggested by any defendant, namely to require that pharma-

[39] In an amicus brief submitted in this case on the first appeal, the Government suggested that consumer deception could be avoided by requiring an imprint on each capsule. It has apparently now retreated from that position.

cists dispense the cyclandelate capsules in the original manufacturers' bottles which identify their source. This suggestion betrays a disappointing lack of familiarity about the dispensing of drugs, and would do an economic disservice to patients. Prescriptions are tailored to a patient's individual and very different needs and are not written in predictable, standard amounts. It is doubtful that generic manufacturers could provide bottles in the very wide range of sizes necessary to accommodate these varied prescription requirements without substantial additional cost, or that pharmacies would reasonably be able to stock these many sizes. This proposal also deprives consumers of the savings that can now be realized when pharmacists purchase drugs in very large quantities, as for example, the 500 and 1,000 capsule bottles in which cyclandelate is available—a quantity far in excess of any prescription that could reasonably be written for a patient. Also, the manufacturers would, by law, be required to provide these bottles with child-proof safety closures. Since patients can request, at the pharmacy level, that some other closure be substituted, each pharmacist would have to stock closures to fit all of the manufacturers' bottles. And, it is not unlikely that, for aesthetic or other reasons, pharmacists would place their own required labels over the original label on the bottles as dispensed. The suggested relief, thus, is not only completely at odds with ingrained physician and pharmacy practice, but would increase the cost and probably decrease the availability of generic and, possibly, all drugs.

The Department of Justice has also urged that banning color copying in the institutional submarket is not necessary. The testimony, however, overwhelmingly established that the truly effective relief, a change in color, would not adversely affect that submarket at all. Institutions are required to purchase by price, not color, and often change the source, and thus the color, of medication without problems. Also, the patient's right to exercise informed

consent, which is undermined by the existence of look-alikes, is just as important to patients treated in an institution as elsewhere.[21] If effected, this relief would also require generic manufacturers to produce their products in two distinct colors, to be provided according to the type of customer ordering. The extra work, and inventory controls required, would undoubtedly also lead to increased cost.

The District Court and the Attorney General also suggest that the penalties set forth in the New York Education law provide sufficient deterrence. On the first appeal, Judge Friendly held that the fact that pharmacists may be accountable under that law does "not necessarily displace the protection for competitors embodied in trademark and unfair competition law". (PA 34a) Any other conclusion would fail adequately to protect Ives and the interests of the public. The Attorney General's own Report shows that the New York State Pharmacy Board gives low priority to the enforcement of the generic substitution law (*supra* p. 11). The record shows only a few indictments in the four year history of the law. Its existence has not had a sufficient deterrent effect in the past, and it is unrealistic to believe that it will in the future. Detection is the problem. Illegal substitution and misbranding of look-alikes goes undetected and unreported by patients who do not know that the illegality has occurred. Most cases of misconduct thus go unchallenged by the Pharmacy Board or prosecutors who, in any event, have numerous other more pressing enforcement obligations.

Defendants' trade association also asserts that the state substitution laws fully accommodate the unfair competi-

[21] The potential for patient deception and confusion exists there, as in pharmacies. Defendant's witness, Ms. Gringauz, acknowledged that, when filling prescriptions in a hospital pharmacy for a brand name drug signed "Dispense as Written", but involving Medicaid reimbursement, she disregards the physician's instructions and fills those prescriptions instead with a generic product. (247-8A, TR 717)

tion laws by requiring that pharmacists label prescriptions to show the drug's source. Not all states have such a requirement. And, even when they do, pharmacists fail to comply. For example, in Premo's pharmacy shop, 14 of 25 pharmacists in New York failed to designate the source of the drug dispensed (*supra*, p. 10).

An injunction against color copying is the only effective relief and the last clear chance to protect the patient receiving a prescription drug. As Judge Friendly noted on the first appeal, it is color that furnishes the only effective direct communication between the manufacturer and the ultimate consumer. If the color is the same, the consumer has no effective way to tell whether he or she has received CYCLOSPASMOL or some generic look-alike. The protection or self-help inherent in the sale of over-the-counter medication is not available. Defendants have cited *Norwich Pharmacal Co.* v. *Sterling Drug, Inc.*, 271 F.2d 569 (2 Cir. 1959), *cert. denied*, 362 U.S. 919 (1960), in which it was held that the defendant could sell its over-the-counter medicine for the relief of upset stomach in the same soothing pink color as plaintiff's medicine. In that case, however, the bottles in which the medicines were sold were of different shapes, the color of the labels and caps differed and the trademarks on the bottles, which could be examined before purchase, were in type large enough to be distinguished at a reading distance of over twenty feet. "It stretches credulity to imagine a purchaser confusing these disparate articles." (271 F.2d at p. 571) It does not stretch credulity to imagine one confusing one blue/red capsule with another blue/red capsule, particularly when they are mislabelled CYCLOSPASMOL.

B. *An Injunction Against Copying the Appearance of CYCLOSPASMOL Is Completely Consistent With the Federal Policy of Encouraging Lawful Competition*

Defendants submit that to require a change in the capsule colors would conflict with the federal policy allowing

the copying of products not protected by patent.[22] They also assert that their ability to compete will be inhibited because of patient resistance to, or refusal of, generic substitutes in appearances different from the innovator products. These submissions do not survive analysis and have no legal or factual support.

The cases principally relied upon to support the first claim are *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111 (1938) and the *Sears/Compco cases*, supra, p. 2 n.2. Under these cases the defendants have the right to sell the drug cyclandelate. Ives has never claimed otherwise. These cases do not, however, condone the sale of the drug in a form or trade dress that fosters deception. On the contrary, they clearly support the countervailing policy, as expressed in the Lanham Act, and in applicable state laws, requiring that copiers take steps to avoid such deception.

In *Kellogg*, the issue was whether a competitor could copy the pillow-shaped form for a shredded wheat cereal product. The innovator had owned a mechanical patent on a machine designed to produce only pillow-shaped biscuits and a design patent covering the pillow-shape. (pp. 119-120) Both patents expired. And, the cost of manufacture would have increased and product quality lessened were the pillow form not used. (p. 122) In the circumstances, the Court held that what was covered by the patents, i.e. a pillow-shape and a machine that was designed to produce only pillow-shaped forms, were free to copy.

However, while allowing copying, the Court also held that "fairness requires that it [the copying] be done in a manner which *reasonably distinguishes its product from*

[22] Although some defendants now argue that their right of free speech has been violated, this claim has no merit. The injunction in this case requires only that they change the color of their capsules. It does not restrict defendants from making any truthful statements they wish about their products.

that of plaintiff." (p. 120, emphasis added) It sanctioned Kellogg's copying because the company used labels with a striking difference, prominently featured its own name, and sold the product in cartons differing in size, form and color. (pp. 120-121) Even the biscuits themselves, although pillow-shaped, were otherwise different in size and appearance. (p. 121)

The *Sears/Compco* cases, *supra*, p. 2 n.2, also specifically address the matter of labelling, passing off and trade dress. The question before the Court in *Sears* was whether a "State's unfair competition law can, consistently with the federal patent laws, impose liability for or prohibit the copying of an article which is protected by neither a federal patent nor a copyright". (376 U.S. at p. 225) In that case, the respondent's design and mechanical patents on a pole lamp were held invalid. The Court held that the article was thus in the public domain and could be copied. For a state to bar copying would be an encroachment on the federal patent system. *Compco*, the companion case, involved a lighting fixture which also had been held entitled to neither a design nor a mechanical patent. The holding was essentially the same as in *Sears*.

It is no exaggeration to say that these cases have been cited in almost every unfair competition case brought since 1964 by defendants seeking to justify almost every kind of commercial chicanery involving copying. While the cases involved federal pre-emption, and did not purport to restrict the applicability of either §32 or §43a of the federal Lanham Act, the defendants here nonetheless argue that the policies expressed in *Sears/Compco* would preclude relief on those federal causes of action as well. They forget that this Court did not preclude entirely the application of even state unfair competition laws. In *Sears*, it held (p. 232):

> "Doubtless a State may, in appropriate circumstances, require that goods, whether patented or unpatented, be labeled or that other precautionary steps be taken

> to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods."

And, in *Compco,* the Court acknowledged that a state "has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original." (p. 238) To that end, it may require that a copier "label or take other precautions to prevent confusion of customers as to the source of the goods". (pp. 238-39) The scope of protection available under the federal law of infringement or unfair competition as embodied in §§32 and 43a of the Lanham Act is surely at least as broad as that allowed to the states under *Sears/Compco.*

The fact that the defendants are free to sell what was covered by the now-expired patent completely protects the public interest and conforms with the policy as expressed in the *Kellogg* and *Sears/Compco* cases. This case does not involve product copying. It involves the copying of the trade dress in which a product has been sold. It has nothing to do with extending a patent monopoly. The patent did not cover, nor even mention, the particular appearance of the Ives' capsules. It covered the drug itself, which is a white powder. Upon expiration of the patent, defendants were free to sell that product in tablet form, or in capsules of any one of thousands of color combinations. The fact that the colors have nothing to do with the patent nor with the characteristics of the *product* during the life of the patent is perhaps best illustrated by the fact that Ives' did not sell cyclandelate in the blue/red capsules until three years *after* expiration of the patent. Yet defendants seek this Court's sanction to copy those

blue/red colors, as well as the blue color of the capsules in which the product was sold during the patent life.

C. *The Capsule Colors Are Not Functional, and Are Not Essential for Effective Competition*

William R. Warner & Co. v. *Eli Lilly & Co., supra,* p. 23, and such other authorities as *Smith, Kline & French Laboratories* v. *Clark & Clark,* 157 F.2d 725 (3 Cir. 1946), *cert. denied,* 329 U.S. 796 (1946), establish criteria for determining whether the appearance of medication is inherently functional. In the first-named case the Court held that the producer of a quinine preparation, colored and flavored with chocolate, could not enjoin use of the color brown for a similar quinine product. The chocolate, which made the preparation palatable and acted as a suspending medium for the quinine, served "a substantial and desirable use, which prevents it from being a mere matter of dress." (265 U.S. at p. 531) There was, the Court held, no "equally satisfactory substitute" for the chocolate, and the brown color imparted to the finished product was the natural color of this essential ingredient. In *Smith, Kline & French Laboratories* v. *Clark & Clark, ibid.,* the appearance of a pill was functional because the scoring and concave bottom allowed its separation into smaller doses; the white color was dictated by the fact that the pill was composed of white sugar-milk; the bevelled edge prevented crumbling, and the roundness of the pill made it less expensive to manufacture.

The blue and blue/red colors of the Ives' capsules are clearly not inherently functional by these standards.[23]

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[23] The National Association of Pharmaceutical Manufacturers has referred to promotional material which purports to emanate from Parke-Davis, a capsule manufacturer. It refers to the psychological effects created by certain colors as used on medication. This document was not introduced at trial, and no testimony established any relationship of the colors blue or blue/red to the therapeutic activity of a vasodilator. Likewise there was no evidence that the blue or blue/red colors had any placebo effect.

Thus, the Court held, on the first appeal, that the case for acquired functionality would depend on what defendants proved at trial.

The Court on the second appeal held that defendants failed to substantiate their excuse for copying based on acquired functionality. The defendants challenge this decision because Judge Mansfield, writing for the majority, noted that the evidence submitted by the defendants on this issue was "unconvincing" and "not persuasive", but did not use the specific words "clearly erroneous" when making holdings contrary to the District Court. This is a matter of semantics. In any event, the findings on Appeal were based not only on uncontradicted facts, but also on defendants' failure to introduce certain crucial evidence, including the testimony of patients, a survey of patient attitudes toward color change, and evidence that color change causes confusion.[24] The Department of Justice has characterized defendants' evidence on functionality as "sparse." (Amicus Br. p. 30) Defendants in other cases have offered not only similar excuses for copying, but, in some instances, even the same witnesses, and the excuses have likewise been rejected, in one instance as "utterly specious," *Boehringer* v. *Pharmadyne, supra,* p. 8 n.8. (211 U.S.P.Q. at p. 1173) Also the error in the District Court's opinion was not only in making findings of fact with no reasonable basis in the record, but also in applying legal standards incorrectly.

The mere fact that some features of a product's appearance may have an incidental use does not and should not mean that it thereby satisfies the legal standard of functionality and may be freely copied, *Time Mechanisms, Inc.* v. *Qonaar Corp.*, 422 F.Supp. 905, 914 (D.N.J. 1976); *Le Sportsac, Inc.* v. *Dockside Research, Inc.*, 478 F.Supp. 602,

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[24] The District Court made no finding of credibility as to any witness. There is not, as suggested by the Department of Justice, a sharp conflict in the evidence submitted on functionality. The Court of Appeals decision was correct even if only the defendants' evidence is considered.

607 (S.D.N.Y. 1979); *Rolls-Royce Motors Ltd.* v. *A. & A. Fiberglass, Inc.*, 428 F.Supp. 689, 692 (N.D. Ga. 1976); *Dallas Cowboy Cheerleaders, Inc.* v. *Pussycat Cinema, Ltd.*, 604 F.2d 200, 203 (2 Cir. 1979):

> "We do not quarrel with defendants' assertion that a purely functional item may not become a trademark . . . However, we do not agree that all of the characteristics of plaintiff's uniform serve only a functional purpose or that, because an item is in part incidentally functional, it is necessarily precluded from being designated as a trademark . . . the feature may become a trademark even though it serves a useful purpose."

Copying of the appearance of a prescription drug likewise is not condoned merely because the color may have some incidental use, or that the shape may serve some incidental useful purpose, *A.H. Robins* v. *Medicine Chest, supra*, p. 7 n.8; see also *Ross-Whitney Corp.* v. *Smith Kline & French Laboratories, supra*, p. 7 n.7.

The basis for defendant's claim of function, and their excuse for exactly copying the appearance of CYCLOSPASMOL capsules comes down to this: patients believe the colors signify therapy and will refuse color change; pharmacists thus will not stock, hospitals will not dispense, and physicians will not prescribe drugs that do not copy the market leader. No patient, however, testified that color signifies therapy. The overwhelming evidence is that any patient inquiry about a color change can be explained satisfactorily by a pharmacist or physician; physicians prescribe regardless of color; pharmacists stock the same drugs in many different colors; hospitals and other institutions buy, and indeed are required to buy, by price, without regard to color; purchasing specifications on the federal, state, and local level throughout the country contain no reference to color, with one exception. (*supra*, pp. 14, 15) Use of color as the means of identification in the emergency room is dangerous, particularly since products with

very different therapeutic ingredients may have a similar appearance. For the same reason the commingling of drugs by patients, and the selection of one or the other thereafter by color is universally condemned. (*supra*, pp. 13-14)

Of the numerous recent cases that have involved this functionality issue, it is only the District Court in this action that accepted the defendants' excuses, without the benefit of any patient's testimony—although the entire basis of the argument is a claimed therapeutic significance of the color to the patient.[25] The majority of the Court of Appeals correctly rejected defendants' unproved claim, as have other courts. *SK&F* v. *Premo, supra*, p. 6 n.4; *A. H. Robins* v. *Medicine Chest, supra*, p. 7 n.8; *Boehringer* v. *Pharmadyne, supra*, p. 8 n.8; *Marion Laboratories, Inc.* v. *Michigan Pharmacal Co.*, 338 F.Supp. 762 (E.D. Mich. 1972) aff'd without opinion 473 F.2d 910 (6 Cir. 1973).

There is, however, another string to defendants' bow. It is easier to compete, they say, if they can duplicate the appearance of the blue and blue/red trade dress. This expansive interpretation of functionality has its apparent basis in cases such as *Pagliero* v. *Wallace China Co.*, 198 F.2d 339 (9 Cir. 1952) in which it was held that the ornamental patterns on china could be copied because "the particular feature is an important ingredient in the commercial success of the product". (p. 343) To require, under this standard, that defendants need prove only that they can sell more by copying than not copying goes far beyond any reasonable test of functionality and in fact would permit all acts of unfair competition or infringement merely because those acts increase sales. As the Court in *SK&F* v. *Premo, supra*, p. 6 n.4, observed of Premo's claim that

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[25] In support of its functionality claim, Inwood relies on material appearing in the supplement to a legal treatise, Callman, The Law of Unfair Competition Trademarks and Monopolies (3rd Ed. 1970). The author of the comments cited is Seymour Kleinman, a member of a law firm that has represented generic drug companies who are also defendants in many of the recent look-alike cases.

copying color made competition easier, "probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound or feel of equity". (625 F.2d at p. 1067)

Of particular relevance is the undisputed evidence of widespread use of different colors for the same dosage form of the same medication by different manufacturers. There is no evidence that their sales have suffered because they do not copy. And, there is no reason why, in the case of cyclandelate, uniformity of color should be expected by physicians, pharmacists and patients, when they do not encounter this phenomenon generally. There certainly is nothing inherent about the fact that this product is a vasodilator. The most widely prescribed vasodilator is available in the same dosage form from different sources in many different colors. Cyclandelate itself is sold by one competitor in an all-red capsule. (*supra*, p. 12)

Defendants, however, have claimed that companies that copy the innovators' products, but not their appearance, market their products differently, by utilizing detail men and advertising. The record does not support this blanket conclusion. (307-8A, 314A) SK & F, for example, has sold a full generic line for several years without duplicating the distinctive appearance of the pioneer drugs, and the testimony was that this line is not detailed. (305-6A, 314A) Even if taken at face value, however, the defendants' argument completely undercuts defendants' claim of functionality, which rests completely on the alleged significance of color to patients. All else follows. To accept defendants' "explanation" about the numerous non-look-alikes on the market, which they claim are sold in a manner different from defendants' products, one must conclude that whether the color means therapy to patients and leads to their acceptance or rejection of a different colored substitute depends on who later copies that drug, defendants or a company using detail men or advertising, although the patient has no way of knowing

how the drug has been promoted. Color change, under defendants' theory, is rejected by the patient if defendants manufacture the drug; it is accepted if a company in the other category manufactures it![36] And, if color indeed signifies therapy or the active ingredient, and availability of more than one color causes concern, how then can Premo explain its copying of *both* colors of two market leaders selling the *same* medication in tablets, one yellow and one peach. (258-9A)

It is also significant that defendant Premo has changed the colors of medication as the result of other litigation, and then merely noted in its price sheets that the colors were new. (607A) Yet no one offered proof at trial that these color changes in any way adversely affected the sale of these products.

Individual manufacturers of cyclandelate, all of whom are enjoined from copying, will not be at a competitive disadvantage.[37] Institutions and pharmacies will continue as they now do, to stock generic drugs whatever their colors. These manufacturers remain free to compete with one another, and with Ives, on the basis of price and quality.

D. *The Relief Granted Is Consistent With and Supports Public Policy; to Deny Such Relief Undermines That Policy*

There is a policy in favor of allowing copying of a product after the patent expires. There is likewise a policy in

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[36] The fact that the non-look-alike product may be sold under a trademark does not affect its availability for substitution. The testimony showed that, under New York law, the less expensive equivalent is to be dispensed, whether or not it bears a brand name. (TR 791-2)

[37] In an interview reported in the October 19, 1981 issue of The Record (Bergen County, New Jersey), Mr. Blackman, president of Premo, is quoted as saying "I would personally not mind if the Supreme Court upheld the decision of the circuit courts. The benefits of being able to hold products to yourself by controlling color is an advantage to major manufacturing and generic companies. It could make our industry more profitable."

various states fostering the availability of generic drugs. The relief granted in this case is consistent with both policies. Cyclandelate will still be freely available, but defendants will have to compete fairly, as does W. E. Hauck Co., by selling cyclandelate in capsules that are not the colors of Ives' capsules.

The inevitable result of allowing the continued sale of look-alike drug products is to keep patients in ignorance of the fact that they are receiving a product different in source and price from that previously dispensed. Patient ignorance, in fact, is exactly what defendants espouse, for they argue strenuously that patients are reluctant to accept change, and that a different color might alert them to the fact that there has been a change. Concealing this is, however, completely inconsistent with the policies of the state substitution laws,[28] and with public policy generally. It negates a patient's right to exercise informed consent as to the medication dispensed to him or her.

In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc., supra,* p. 34, this Court recognized the importance of patient access to information about the pricing of drug products. The Court's reasoning applies with equal force to this situation in which patients are being kept in ignorance of perhaps an even more important aspect of health care, namely the true source of their medication (425 U.S. at p. 770):

> "There is, of course an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them."

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[28] Respondent, in any event, questions whether issues of state public policy raised by Petitioners and amici are relevant in determining whether a cause of action under federal law has been established.

The concealment of change resulting from the dispensing of look-alikes also violates the policy of the State of New York,[39] as expressed in *Pharmaceutical Society of the State of New York* v. *Lefkowitz*, 586 F.2d 953 (2 Cir. 1978). The purpose of the New York substitution law is to permit prescriptions to be filled with less expensive equivalent drug products when a physician is willing to permit use of the substitute. The law was not intended to interfere with a patient's informed choice of medication (586 F.2d at p. 958):

> "The decision to use a brand name or generic drug and which brand name to use, remains as before with the doctor and the patient; the provisions of the Generic Drug Act only come into play *after* their initial choice (usually that of the doctor) has been made between 'dispense as written' and 'substitution permissible'. Here, as under prior law, there is no deprivation of the right of the patient, with the advice of his or her doctor, to decide on the proper medication."

That choice is negated in instances of undetected illegal substitution. And, the aim of lowering drug costs is thwarted where a generic is substituted, as authorized, but an adequate cost saving is not forthcoming, and the patient is not alerted to inquire. There is no generic substitution law requiring that the fact of substitution be concealed from the patient, which is the aim of defendants' practices; on the contrary all require, in one form or another, that the patient be informed.

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[39] Attorney General Abrams' assertion that New York State public policy favors the availability of generic drugs in look-alike colors lacks credence. Neither the New York generic substitution law, nor any other law, makes such a requirement. Also, the Attorney General's statement is inconsistent with the purchasing practices of state institutions, none of which require color in their bidding specifications, supra p. 15. The conclusions in his brief assume the validity of defendants' claim that patients will not accept color change in their medication, whereas the record herein shows that this is not so.

The sale of these drugs in look-alike capsules also allows a manufacturer to avoid accountability for the quality of its products. It exposes Ives to the risk of physician or patient dissatisfaction with the look-alike capsules, particularly those which have been dispensed and labeled with Ives' trademark, and to the further risk of suit,[30] against it, "the deep pocket defendant," *SK & F* v. *Premo, supra,* p. 6 n.4 (625 F.2d at p. 1066). This concern applies whether or not proof has been offered as to the present equivalence or nonequivalence of the drugs, *Hoffman LaRoche* v. *Premo, supra,* p. 6 n.4 (210 U.S.P.Q. at p. 382). It is well established that a manufacturer should not be forced to place its reputation in the hands of another over whom he has no control, *Yale Electric Corp.* v. *Robertson,* 26 F.2d 972 (2 Cir. 1928).

III.

Ives Has Also Established a Right to Relief Under §43a of the Lanham Act and the New York State Law of Unfair Competition.

This case is in an unusual posture. Ives claimed that defendants were liable on three causes of action. The Court of Appeals decided only the contributory infringement claim. The Department of Justice in its Brief Amicus suggests that the Court should instead have decided the § 43a claim, and asks that this Court remand this case for consideration of that claim, with guidelines setting forth the scope of liability under §43a.[31] Ives submits that the finding

[30] Although Ives did not submit evidence as to equivalence, it should not have to risk its reputation on the future quality of the look-alikes. An FDA inspection in 1978 showed, for example, that Inwood had significant deviations from good manufacturing practice, indicating a lack of control over manufacturing, testing and release of drug products. (FDA Establishment Inspections, 6/19-23, 26-30; 7/5-7, 18-21, 26-28, 31 and 8/1-4, 7 and 8, 1978) In 1981, Inwood manufactured cyclandelate capsules that failed weight variation tests. (FDA Establishment Inspections, Sept. 3, 4, 8 & 11, 1981).

[31] The Department of Justice also asks this Court to hold that defendants are not liable for damages or an accounting of profits.

of contributory infringement is completely justified. However, it is equally clear that Ives also proved its case under §43a.[12]

The Court on the first appeal held that defendants would be liable under §43a if Ives proved that the capsule colors had acquired secondary meaning, and if they were not functional. The functionality issue has already been addressed by the Court of Appeals, which held that the proofs offered by the defendants to justify copying—which were based on the alleged functionality of the capsule appearance—were "unconvincing" and "not persuasive." Ives also clearly proved secondary meaning. The capsule colors were completely arbitrary when selected, with no relationship to the ingredients or therapy of the product. There were extensive sales of CYCLOSPASMOL cyclandelate in blue and blue/red capsules, and starter samples showing the trademark CYCLOSPASMOL and identifying Ives as their source were distributed to patients. The colors, with the trademark and the Ives name, were depicted both in a widely used medical reference book and a Guide to prescription drugs for laymen. (*supra*, p. 5)

Perhaps the best proof that the colors had come to signify CYCLOSPASMOL capsules, however, is the fact that

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This issue is completely premature. On remand, the District Court held that plaintiff was entitled to damages and an accounting, but stayed the proceeding which will determine the extent of that liability pending the outcome of this appeal. The Court of Appeals itself never considered the question of damages and an accounting, and presumably cannot do so until the appeal, if any, from the final decision of the District Court after a hearing on that issue. In any event, particularly given the specific finding of intent on the part of defendants, such an award would certainly be justified.

[12] Since the Court of Appeals has not decided the claim, it is technically not before this Court and an extended discussion of the §43a theory of liability does not appear to be appropriate. However, should the Court decide to consider the §43a claim, despite the fact that the Court below did not do so, Ives seeks permission to submit a supplemental brief on that issue.

the defendants deliberately copied those colors. Were they not associated with CYCLOSPASMOL, there would have been no reason for them to do so. The excuses offered by defendants to justify the copying were rejected by the Court of Appeals. In the circumstances, secondary meaning had been clearly proved by the same kinds of evidence correctly accepted in *SK&F* v. *Premo, supra,* p. 6 n.4; *A.H. Robins* v. *Medicine Chest, supra,* p. 7 n.8; and *Boehringer* v. *Pharmadyne, supra,* p. 8 n.8.

Although the Department of Justice asserts that the Ives survey of physicians and patients was the sole evidence of secondary meaning submitted, in fact the survey merely corroborated what the other evidence, as aforesaid, had already established. Specifically it established that, when shown blue and blue/red capsules, physicians and patients will misidentify those capsules as CYCLOSPASMOL because of the color.

Ives' third cause of action was based on state unfair competition law. Under New York law, which applies in this case, the deliberate copying of arbitrary trade dress will be enjoined without independent evidence of secondary meaning, *Perfect Fit Industries, Inc.* v. *Acme Quilting Co., Inc.,* 618 F.2d 950, 953-4 (2 Cir. 1980):

> ". . . monopolization is not a problem in the realm of trade dress, because the possible varieties of advertising display and packaging are virtually endless. Thus, in this area New York law has concerned itself principally with whether or not the public is likely to be confused, rather than with whether the first comer's trade dress has acquired secondary meaning.
>
> • • •
>
> "If there was intentional copying the second comer will be presumed to have intended to create a confusing similarity of appearance and will be presumed to have succeeded."

Ives submits that it established liability under this cause of action as well. Public policy would not bar the relief. On the contrary, to allow the continued sale of look-alikes, and thereby conceal the fact that a generic masquerading as the innovator has been dispensed, would undermine the policy of the state substitution law, as aforesaid. Should this Court remand the case to the Court of Appeals for consideration of the §43a claim, respondent asks that the remand include a direction to determine the New York claim as well.

CONCLUSION

Respondent, Ives Laboratories, Inc., submits that the decision of the Court of Appeals was in all respects correct, and should be affirmed.

Respectfully submitted,

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Nos. 80-2182 and 81-11

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1981

INWOOD LABORATORIES, INC., *et al.*,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

DARBY DRUG CO., INC., *et al.*,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

Certificate of Service

I hereby certify that on this day of January, 1982, three copies of the within Respondent's Brief with revised record references were served by first class mail postpaid on each of the following: Bass, Ullman & Lustigman, Attorneys for Petitioner Inwood Laboratories, Inc., 747 Third Avenue, New York, New York 10017; Kirschstein, Kirschstein, Ottinger & Cobrin, Attorneys for Petitioner Premo Pharmaceutical Laboratories, Inc., 666 Fifth Avenue, New York, New York 10103; and Salon, Marrow & Dyckman, Attorneys for Petitioners Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Co., Inc., 41 East 42nd Street, New York, New York 10017. I further certify that all parties required to be served have been served.

/s/ MARIE V. DRISCOLL
Marie V. Driscoll

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No. 80-2182
No. 81-11

IN THE SUPREME COURT OF THE UNITED STATES
October Term, 1981

INWOOD LABORATORIES, INC., and PREMO PHARMACEUTICAL LABORATORIES, INC.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF OF PETITIONER INWOOD LABORATORIES, INC.

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No. 81-11

IN THE SUPREME COURT OF THE UNITED STATES
October Term, 1981

INWOOD LABORATORIES, INC., et al.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

REPLY BRIEF OF PETITIONER INWOOD LABORATORIES, INC.

I. THIS COURT SHOULD DEFINITIVELY RESOLVE THE CONTROVERSY BETWEEN THE PARTIES

Contrary to the contention of Ives Laboratories, Inc. ("Ives") and its amici, brand-name drug companies have the burden to justify their request for a monopoly of color not subject to patent, copyright or trademark protection. The lower court held that petitioners' advertising catalogs "suggested by implication" that pharmacists engage in unlawful conduct. Petitioners, including Inwood Laboratories, Inc.

("Inwood"), were therefore held liable as "contributory infringers." Relying heavily on the reasoning of a series of cases decided in the United States District Court for the District of New Jersey,[1] Ives abandons the Second Circuit's analysis[2] and argues that mere similarity of capsule color is enough to establish contributory liability since petitioners could have anticipated that such similarity would make it easier for some pharmacists to engage in unscrupulous conduct. This Court is thus asked to affirm the finding below on the alternative

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[1]See cases cited in Inwood's Main Brief at 42, n.77.

[2]Paradoxically, the amicus brief of the Pharmaceutical Manufacturers Association ("PMA") in effect concedes the error of the Second Circuit's opinion. PMA therefore asks this Court to dismiss the writ of certiorari. This argument is patently frivolous. That the Second Circuit by all accounts decided the case improvidently requires that its decision be reversed, and not that the writ be classified as having been improvidently granted.

rationale and even the supposed record of the cases decided in New Jersey.[3]

Although urging affirmance on an alternative ground to find liability under §32 of the Lanham Act [15 U.S.C. §1114], Ives argues that this Court avoid any review of the §43(a) [15 U.S.C. §1125(a)] issues presented in this case.[4] It would not serve the interests of justice to leave for another day issues which are necessary for a definitive resolution of the pharmaceutical color/trademark controversy. Judicial economy requires that one rule be established for determining the theory of contributory liability, whether under §32 or §43(a). In the absence of contributory liability under

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[3]See PMA Brief at 14-15, 23-26.

[4]Ives' avoidance of §43(a) is inconsistent with its reliance on the New Jersey cases which, as it admits, are based inter alia upon a violation of §43(a). See Ives Brief at 25.

federal law, the "Sears/Compco"[5] principles dictate that any state law unfair competition theory which Ives may have must fail. This Court is also in as good a position as the District Court and the Court of Appeals to review the documentary evidence which fails to show any secondary meaning for the colors blue and blue/red.[6] Even assuming secondary meaning of some sort, its only relevance as expressly found in the New

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[5]Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964); Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964).

[6] "It ought not to be presumed that because, thanks to a patent, all the supplies of a drug have for a considerable period come from the patentee, therefore the public want[s] the drug made by him, rather than just the drug." W.R.Cornish, "Same Again--Same Substance of Same Maker?" [1972] BRIT. BUSINESS LAW J. 141, 142.

See also R. Chambers, "Colours--The Drug Companies Seek Protection" [1976] NEW ZEALAND L.J. 472, 476 (Nov. 2, 1976) (noting that "colour is an important means of identification of the drug, rather than of the drug's source of manufacture.") [emphasis in original]; Inwood's Main Brief at n.49 and accompanying text.

Jersey cases is the extent that it contributes to a manufacturer's liability for the acts of pharmacists who unlawfully dispense its product. The issues which must necessarily be decided by this Court, in light of the alternative theory of contributory liability advanced by Ives, thus encompass all of the elements needed for resolution of the overall controversy.

Finally, it is of the greatest importance that this Court definitively determine these issues. Presently, the historical practice of utilizing similar colors[7] has been subjected to successful challenge in a barrage of litigation against the generic drug companies. Petitioners ask this Court to hold that copying of capsule or tablet

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[7]Neither Ives nor its amici make any effort to challenge the uncontradicted testimony that this has been the general practice for more than 40 years. See also Zenith Laboratories, Inc. v. Eli Lilly & Co., 460 F.Supp. 812, 819 (D.N.J. 1978).

color is permissible as a lawful aspect of competition in the prescription drug industry.[8] Generic companies must be in a position to know at the very outset whether their decision to utilize particular colors will be lawful.[9] They cannot afford to take the risk that their decision will be challenged on a case-by-case basis as each brand-name company separately seeks to establish that its colors are entitled to protection. Knowing that the smaller generic companies are unable to bear the financial burden inherent in multiple

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[8]Color performs various functional purposes in the distribution and use of prescription drugs. For fully effective competition, such use should not constitute liability under §32 or §43(a) of the Lanham Act.

[9]This Court's decision will have vast and imminent ramifications for the drug industry. Ten prescription drugs, including Valium, which are due to come off patent in the next four years involve annual sales of over $1 billion. See "Competition in the Drug Industry," Hearings before the Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, No. 97-35 (97th Cong. 1st Sess., Mar. 10, 1981) at 13.

litigation of this kind, brand-name companies have already obtained a series of consent judgments against continued utilization of similar drug colors.[10] Inwood therefore respectfully requests that this Court reverse the Ives IV decision and definitively reject the arguments advanced by Ives and its amici which seek to obtain a color monopoly for unfair competitive purposes.

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[10]See, e.g., Ives Laboratories, Inc. v. Bioline Laboratories, Inc., Civ. Action No. 81-914 (D.N.J. Consent Judgment entered against defendant Henry Schein, Inc. Oct. 15, 1981); American Cyanamid Co. v. Par Pharmaceutical, Inc., Civ. Action No. 81-1001 (D.N.J. Consent Judgment entered June 17, 1981); Bristol-Myers Co. v. Par Pharmaceutical, Inc., Civ. Action No. 81-290 (D.N.J. Consent Judgment entered Apr. 14, 1981); Boehringer Ingelheim, G.m.b.H. v. Chelsea Laboratories, Inc., Civ. Action No. 80-3759 (D.N.J., Consent Judgment entered Feb. 10, 1981); Schering Corp. v. Zenith Laboratories, Inc., Civ. Action No. 80-2546 (D.N.J. Consent Judgment entered Sept. 19, 1980).

II. THERE HAS BEEN NO SHOWING OF TRADEMARK INFRINGEMENT UNDER THE SECOND CIRCUIT'S THEORY OF LIABILITY

The most obvious reason for Ives' abandonment of the Second Circuit's reasoning concerning contributory trademark infringement[11] is that its finding was premised on the theory that trademark infringement was shown by the "additional evidence" of so-called "mislabeling." As shown in Inwood's main brief (without any contradiction by Ives and its amici) all pharmacists, pursuant to a prescription which authorized

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[11] It also enables Ives to avoid the critical question of whether the Second Circuit impermissibly restricted petitioners' First Amendment rights. In addition to the cases cited at pp. 39-41 of Inwood's Main Brief, see also Farm Service, Inc. v. United States Steel Corp., 90 Ida. 570, 414 P.2d 898 (1966); Universal City Studios, Inc. v. Ideal Publishing Corp., 195 U.S.P.Q. 761, 762 (S.D.N.Y. 1977). See generally D. Karl, "First Amendment Considerations" appearing in Practising Law Institute Handbook #141, Generic Trademarks 53-68 (December 1981). Ives now claims it never intended to restrict the exercise of petitioner's free speech rights. But see Ives' Complaint at Count III [J.A. 22-23].

generic substitution, dispensed the appropriate generic product when available. A few placed the word "Cyslospasmol" on the container accompanied by written and/or oral notice that the product was "generic Cyclospasmol." This additional evidence was supposedly critical to the finding of contributory trademark infringement since the earlier evidence relating to "illegal substitution" had expressly been found in Ives II to be insufficient to establish contributory liability. Ives II at Pet.App. 36a, 52a-53a.

Ives makes no direct response to the threshold issue that there must be a showing of primary trademark infringement before finding liability for contributory infringement. Both Ives and PMA merely state that since the word "Cyclospasmol" appeared on the dispensing label there was per se trademark infringement. In so doing, they read out of §32 the requirement that Ives has the

burden of proving likelihood of confusion.[12] This position is clearly in error. The support which it impliedly finds in the Ives IV opinion profoundly and adversely affects the lawful, comparative use of trademarks.

Ives relies on Boehringer Ingelheim, G.m.b.H. v. Pharmadyne Laboratories, 211 U.S.P.Q. 1163 (D.N.J. 1981), wherein the court stated that it was not certain that the words "generic Persantine," were sufficient to advise consumers that a generic rather than the brand-name drug was being dispensed. The court there believed that "generic Persantine" might not be understood, even though consumers were told orally by the pharmacist that they were getting a generic product at a lower price.

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[12] See Fisher Stores, Inc. v. All-Nighter Stove Works, Inc., 626 F.2d 193, 194 (1st Cir. 1980); American Footwear Corp. v. General Footwear Co., Ltd., 609 F.2d 655, 664 (2d Cir. 1979), cert. denied, 445 U.S. 951 (1980); Telemed Corp. v. Tel-Med, Inc., 588 F.2d 213, 216 (7th Cir. 1978).

Curiously, the court stated that only the words "generic for Persantine" would be sufficiently descriptive and explanatory to the patient.[13] Id. at 1181.

There is no basis in law for permitting judicial speculation that a consumer might not understand one of the most elementary and basic concepts in the field of prescription medications in lieu of an evidentiary finding of likelihood of confusion. The prescriptions involving "mislabeling" all authorize substitution, which presumes that the physician had advised the patient that a generic would be dispensed.[14] The

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[13]Thus, the very case cited negates the per se approach in favor of purportedly determining when confusion exists. Moreover, the court's discussion of the issue was entirely speculative since the brand-name company there, as here, introduced no evidence relating to this matter.

[14]See Pharmaceutical Society of State of New York v. Lefkowitz, 586 F.2d 953, 956 (2d Cir. 1978) (Mansfield, J.). See also N.Y.EDUC. LAW §6810(6)(b) (McKinney's Supp. 1981) [Pet.App. 115a].

assumption that patients so informed by their physicians, reminded by the pharmacist that a "generic" was being dispensed, and having paid a lower "generic price"[15] would still not understand what was transpiring is totally unrealistic.

Similarly, the so-called "freedom-of-choice" argument raised by Ives and the amici is totally misplaced. It is the physician's responsibility to advise the patient that a generic will be dispensed. Ives and incongruously, the American Association of Family Physicians, assume, without any basis, that physicians as well as pharmacists will violate their legal and ethical responsibilities, and that a change in capsule color

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[15]PMA's contenion that there is no such thing as a generic price is in error, as shown by the adoption of generic substitution laws in 49 states which mandate that a lower generic price be charged. New York State also requires that pharmacists must post the brand-name versus generic sale price of the 150 most frequently prescribed drugs. See N.Y.EDUC. LAW §6826 (McKinney's Supp. 1981).

is necessary to compensate for the physician's dereliction.

It was Ives' burden to show by a preponderance of the evidence that a likelihood of confusion existed. No such evidence was introduced, and post hoc speculation cannot correct the manifest error in the Second Circuit's finding of per se trademark infringement in the use of the term "generic Cyclospasmol." Justice Holmes clearly stated the law to be applied, which Ives blithely ignores:

> "When the mark is used in a way that does not deceive the public we see no such sanctity in the word as to prevent its being used to tell the truth. It is not taboo." Prestonettes, Inc. v. Coty, 264 U.S. 359, 368 (1924) [emphasis added].[16]

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[16] See also Judge Untermeyer's scholarly dissenting opinion in Winthrop Chemical Co. v. Blackman, 246 App.Div. 234, 285 N.Y.S. 443 (1st Dept. 1936). Cf., §33(b)(4) of the Lanham Act [15 U.S.C. §1115(b)(4)].

III. THE BRAND-NAME COMPANIES' ABSOLUTE DENIAL OF FUNCTIONALITY FOR PHARMACEUTICAL COLORS CANNOT BE SUSTAINED

Ives advances the absolute position that despite the findings of the district court there is no functionality for colors in the context of prescription pharmaceuticals. Any concession of functionality would necessarily defeat a finding of liability in this case, since Ives has abandoned the rationale of the Second Circuit that liability can be premised on certain unidentified suggestions in petitioners' respective promotional materials. It would be manifestly unfair to hold petitioners contributorily liable for the acts of unscrupulous pharmacists, if petitioners selected the capsule colors for legitimate competitive reasons. Various aspects of color functionality are proven in this record and by all of the available evidence. This Court should reject Ives' denial and

confirm the role of color as a functional aspect in the commercial and therapeutic success of petitioners' products.

Ives' principal contention is that such functionality can only exist by deceiving the patient. This argument totally misrepresents the record. The trial testimony cited in detail in Inwood's main brief addressed the issue of the effect of a change in capsule color upon patients who are informed that they are obtaining a generic product. There is absolutely no element of deception with respect to this aspect of functionality.

The nature of competition between generic companies and their brand-name counterparts is such that this issue of functionality arises when patients, having previously taken a brand-name product under a prescription which prevented substitution, either on their own initiative

or at the suggestion of their physician, obtain a renewal prescription which for the first time authorizes generic substitution. Patients, knowing that a generic has been dispensed, most frequently discover any difference in color at home, when the product is first used.

Mandatory color differences thus impose the following penalties on patients who in consultation with the physician have opted to at least try a less-expensive generic. Patients will at first believe that a mistake had been made in filling the prescription. Patients must then call or visit the pharmacist and/or the physician to obtain an explanation. More rational patients are thereafter expected to accept the explanation that a change in color should not affect therapeutic efficacy. After all hurdles have been overcome, patients must then evaluate the efficacy of the generic

in comparison to their experience with the brand-name product. Patients are concerned: "Will this product produce the same or different therapeutic effect?" Their eyes tell them every time they look at the medicine that the product is different.

Significant in this respect is the less than ethical campaign of the brand-name companies to plant unfounded fears in the minds of the public about the efficacy of generic drugs. See, e.g., PMA brief at 17-20; Inwood Exh. 6 at 289-307. The myth of brand-name superiority over generics fostered by "fear and smear" tactics has been completely refuted.[17] See FDA Office of Planning and

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[17]FDA investigations have disclosed that Ives' Isordil has failed to perform its therapeutic functions on various occasions. See FDA Establishment Inspection Reports dated Mar. 31, 1977 and Jan. 25, 1979. Ives' cyclandelate, on another occasion, was found to have had unexplained side effects on a patient and in other instances Cyclospasmol capsules were covered by a mold with a strong odor. See FDA Establishment Inspection Report dated Nov. 2, 1978. Moreover, FDA records

Evaluations, "An Analysis of Prescription Recall Rates" (Apr. 1980) (concluding no difference in quality between generic drugs and their brand-name counterparts). See also Remarks of FDA Commissioner Kennedy reported in "HEW News," P78-34 (Sept. 13, 1978) ("[there is] no difference in the recall records of brand versus generic drugs."). In fact, it is well known that many so-called brand-name products are actually manufactured under contract by

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(cont.)

show that in 1981 alone, PMA members (including E.R. Squibb, Eli Lilly, Abbott, Hoffman-LaRoche, Upjohn, Pfizer and Mead-Johnson) conducted at least 27 recalls of their "superior" products, due to, for example, non-sterility, sub-potency, lack of homogeneity, mislabeling and the curdling of infant formula. See FDA Enforcement Reports (1981).

generic companies.[18] Yet, the brand-name company attack on generic drugs continues unabated. A patient who decides to try a generic is thus likely to be sensitized to expect a potential difference between brand-name and generic drugs. The further penalty of a difference in color may very well be the straw that breaks the camel's back.[19]

Ives' insistence that a difference in

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[18] See, e.g., Inwood's Exh.6 at 155-56 (noting Mylan manufactures Erythromycin for three PMA members for distribution under their brand name. Mylan sells the same product to petitioner Sherry. The branded versions of the identical product sells at retail for 2 or 3 times more than the generic product.) See also "Drug Product Selection," Staff Report to the Federal Trade Commission (Bureau of Consumer Protection, Jan. 1979) at 51-54.

[19] Ives suggests that physicians should advise their patients that the medicine they get under a generic prescription may be in a different color. Since patients know they will be receiving a generic, there is no reason for it to be in a different color. Moreover, communicating a color difference will not resolve, and may even emphasize, the patient's potential adverse reaction to this difference. Requiring physicians to make such explanation is another burden which the brand-name companies can promote as a reason for not prescribing generically. See also n.26, infra.

color will not matter to the patient is an attempt to deny a commonly recognized and indisputable scientific fact. At a major symposium sponsored by the American Medical Association to discuss the issue of bio-equivalence of comparable drugs, it was noted:

> "DR. SCHIFFMAN [Director of Medical Terminology, American Medical Association]: [p]atient acceptance, not only of medications but of the doctor himself, ... are a real part of medicine and are extremely important.
>
> "For example, Dr. Barclay who is an Assistant Executive Vice President of the AMA and who has been a practicing physician for a number of years, feels very strongly about this. He believes that a patient definitely can be influenced by the appearance of a medication. You know the old story about the 'little old lady' who receives a different color tablet than the last one she got. Her response is, 'The pink pill is not doing me any good Doc, whereas the green one was great.' I am told that this is not a straw man; it is a real effect. This is an intangible that must be taken into account in any type of equivalency program you devise.

* * *

"DR. WAGNER [Professor of Pharmacy, American Society for Clinical Pharmacology & Therapeutics]: [U]pjohn sells PAC's: one green, one white. Now, if you put a patient on the green, you will never convince them that the white is the same. It has happened so many thousands of times, that people just gave up trying to convince the patient otherwise. So, they produce them both. You cannot switch a patient once they're on one, because they just will never believe that it is the same pain killer.

"Every pharmacist in this room, who has ever practiced, has seen the look on the 'little old lady's' face if she gets the 'wrong-colored pills,' or tablets. If you haven't been in a pharmacy and seen this, then you shouldn't even be commenting on the subject . . . Patients are horrified, and it is a big shock to them .... Now, it may be unimportant to you as a scientist, but it is very important to the 'little old lady.'" See "The Scientific Evaluation of Drug Equivalency", Proceedings of a Colloquium - Washington, D.C. - June 14, 1974 (A. Brest, Editor, EXCERPTA MEDICA, Wash. D.C., 1974) at 58-59, 65 [emphasis added].[20]

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[20]As one commentator recently noted in discussing this Court's review of Ives IV:

"In the middle [of this controversy] are, perhaps, millions of financially strapped

Ives' own witness confirmed the patients' association of color with their comparative efficacy evaluation of medicines:

> "It is very simple. There are sometimes when you're talking to a patient and they say to you, gee, you know, the last batch of red tablets you gave me weren't quite as good as the green batch." [Tr. 364, J.A.188a]

In more candid moments, the brand-name companies themselves recognize the very functionality which they so strenously deny in this case. A leading manufacturer of pharmaceutical capsules (and a member of PMA) is Parke-Davis, which has extensively promoted the functionality of capsule colors in its publication "Capsule Color

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> elderly patients with, in many cases, fading eyesight, who identify their heart pills by their color to distinguish them from their liver pills and their stomach pills." Dickinson, "Washington Report" PHARMACEUTICAL TECHNOLOGY, Oct. 1981 at 23.

Considerations" (Parke-Davis, Division of Warner-Lambert Co. 1980) ("Parke-Davis"):[22]

> "Parke-Davis Can Provide You with the 'Color-Edge'
>
> "Our color laboratory, our equipment and our color experts are at your command to come up with the right colors for you. Contact our technical sales representative. Show him the color combination you have in mind . . . . If you need guidance in psychologically appropriate colors, we can provide several papers on the subject. Better still, let our color consultants come up with a few suggestions." Id. at 3.

Patient compliance (also referred to by Parke-Davis)[23] is an additional critical

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[22]This publication is on file in Warner-Lambert's corporate services library. See letter from Jacob Laufer to Edith Chapman, January 27, 1982.

[23]The Parke-Davis material which has been filed with the Court also notes:

> "Numerous investigations in the U.S., England and Continental Europe have established that patients show preferences -- and aversions -- to various colors.
>
> • • •
>
> "Two-color capsules indicate a change from one condition to another. Again, using red and dark blue as examples, red conveys irritation and inflammation and dark blue represents sedating these conditions. Because the therapeutic effect is conveyed by the use of two colors -- and because two colors provide

factor in an understanding of functionality of color. The trial testimony demonstrated that patient compliance with doctor's instructions is frequently poor. [Tr. 829, J.A. 279a] See also Blackwell, "Treatment Adherence" 129 BRIT.J.PSYCH. 513, 517 (1976). Consequently, a change in color which causes a negative reaction in patients must have an adverse reaction on the already poor rates of patient compliance.

(cont.)

more accurate identification, most pharmaceutical manufacturers favor two colors.

"While the functional choice of two colors to express the action of the preparation is of paramount importance, asethetically pleasing color combinations also should be selected whenever possible. Patients also respond positively to such combinations.

"A capsule which, through it color(s) conveys psychologically that it will be beneficial, builds patient confidence in the preparation. This leads to better patient compliance." Id. at 2. Accord, Buckalew & Coffield, "An Investigation of Drug Expectancy as a Function of Perceptual Characteristics" (Manuscript submitted for publicaton, Alabama A&M, 1982).

No substantive response to the undeniable scientific evidence is made by Ives.[23] PMA argues that the colors here do not serve a psychological purpose because Ives claims they were arbitrarily selected. Ives similarly argues that these specific colors have not been shown to have a placebo efffect.

Both arguments are clearly wrong. Capsule color has its effect on therapy, irrespective of whether the manufacturer selects the colors for that purpose. Ives' reliance on testimony that similarity of

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[23]See also Jacobs & Nordan, "Classification of Placebo Drugs: Effect of Color," 49 PERCEPTUAL & MOTOR SKILLS, 367-372 (1979); Blumenthal, Burke & Shapiro, "The Validity of Identical Matching Placebos," 31 ARCH.GEN.PSYCH., 214 (Aug. 1974); Biron & Caringnan, "Chromo Confusion: A New Type of Pill - Pill 'Interaction' in Cardiology," 110 CMA JOURNAL, 1346-48 (June 22, 1974); Schwartz, "The Elderly Patient and His Medications," GERIATRICS, 517 (June 1976); 47 F.R. 444, 447 col.2 (Jan. 5, 1982) (FDA panel notes that major drawback in use of activated charcoal as anti-toxin is its black color, which often causes children to refuse it); 46 F.R. 47,623 col.3 (Sept. 29, 1981) (discussing color coding labeling requirements for blood and blood components).

color is not medically necessary thus misses the point. The issue is not whether similarity of color is absolutely necessary but, rather, whether it is desirable and beneficial. Patients who receive generic drugs should be entitled to have the same psychological color support as patients who receive a brand-name medication.

PMA has also urged this Court to consider the series of New Jersey cases dealing with this issue, but it intentionally omits the direct evidence in those cases that the brand-name companies have adopted the very criteria discussed above by Parke-Davis and in the scientific literature. PMA members utilize these criteria in both the selection

and promotion of their drug colors.[24]

The arguments against color similarity ignore the basic problem; that color monopoly is at the heart of the promotional

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[24]A document authored by PMA member Merck was filed in opposition to Merck's motion for summary judgment in the case of Biocraft Laboratories, Inc. v. Merck & Co., Inc., ____ F.Supp. ____, Civ. Action No. 77-693 (D.N.J. Oct. 2, 1980), and discloses the following:

> "The psychological importance of color to a patient has been documented." Doc.Prod. #M39257 [emphasis added].
>
> * * *
>
> "Color is thought to be psychologically important to the patient . . . Brown and grey are not well-accepted colors because of their association with dirt and death. Well-accepted colors include light blue, peach and a light red." Doc.Prod. #M39259 [emphasis added].
>
> * * *
>
> "Physicians have also documented studies associating potency with color (i.e., red)." Doc.Prod. #M39267.
>
> * * *
>
> "Proper choice of color is particularly essential in physchotherapeutic agents. Marketing should refer to past studies on selection of color." Doc.Prod. #M39271 [emphasis added]. See Exh.24 in Opposition to Merck & Co.'s motion for summary judgment; Merck internal memorandum and attachments from J.E. Allegretti to RIMM members, dated Aug. 29, 1978.

efforts of brand-name companies to convince their accounts, including physicians, not to buy generic substitutes. One PMA member, for example, succeeded in persuading pharmacists and a medical center not to purchase competitive products on account of its products' claimed color advantage.25

Doctors have publicly and frequently testified concerning their opposition to potential switches in the color of

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25See Exh.4, 9 and 10 filed in opposition to Merck's motion for summary judgment; Merck Product Related Information Memo, No. 13 at 1-3 (Mar. 4, 1976), Doc.Prod.#M21933-M21935; Region Managers' Activities Report, Monthly Summary, at 7 (May 1976), Doc.Prod.#M20832; Region Managers' Activities Report, Monthly Summary, at 4 (Feb. 1976), Doc. Prod.#M20817. Despite such evidence, summary judgment sanctioning a monopoly of color was granted. See Biocraft Laboratories v. Merck, supra. It is clear that some district courts have construed SK&F Co. v. Premo Pharmaceutical Laboratories Inc., 625 F.2d 1055 (3d Cir. 1980), as a mandate to disregard any evidence of color functionality. For another extreme example of this unfortunate consequence, see Artus Corp. v. Nordic Co., 512 F.Supp. 1184, 1189 (W.D.Pa. 1981) (plaintiff permitted to acquire monopoly for 14 colors where entire industry used 14 colors to identify thickness of construction materials).

prescription drugs. For example, Dr. John Budd, then President-Elect of the American Medical Association testified before Congress that:

> "Such factors as differences in the dosage form or in taste, color, size, or shape of a tablet can be critical in determining whether the patient will 'take' the prescribed medicine." "Prescription Drug Labelling & Price Advertising," Hearings Before the Subcomm. on Consumer Protection and Finance for the House Comm. on Interstate & Foreign Commerce No. 94-153, at 286 (94th Cong., 2d Sess., Aug. 30, 1976).[26]

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[26]Dr. Budd also stated:

> "However, I encountered frequently the annoying situation that a patient would have the prescription filled elsewhere and get a tablet or capsule or a medication that appeared different from the one he had been used to getting, and then he would phone me and ask why I had changed the drug, or had the pharmacy made a mistake? I would have to phone the pharmacist and find out what was actually prescribed, and then phone the patient and tell him, yes he had a different brand, but essentially the same drug.
>
> "For many physicians, this is extremely irritating when they write generic prescriptions, this constant phoning back and forth on the part of the patient, because each time he has the prescription filled he might

One of the more ironic examples of inconsistencies in the denial of color functionality is found in the brief of amicus Medicine in the Public Interest ("MIPI"). MIPI claims that color plays the least important role in medical treatment. MIPI's counsel must have been unaware that Dr. Louis Lasagna (who is identified as a member of MIPI's Board of Directors in the booklet it filed with the Court) has published in a scientific journal his view that drug identification by color for the patient is of great importance to avoid confusion and for effective communication by physicians to patients. To apply Dr. Lasagna's approach would require prescribing by brand name only. See Mazzullu & Lasagna, "Take

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(cont.)

get a different appearing tablet. Patients are anxious enough about their illness, and it is unfair to load on them the further anxiety that perhaps a mistake was made in filling the prescription." Id. at 291 [emphasis added]

Thou . . . But is Your Patient Really Taking What You Prescribed?", DRUG THERAPY at 11-15 (Nov. 1972).[27]

In addition, the record presents abundant evidence that uniformity of color would have other significant functional advantages in the public interest. Comingling of medications in a single container for the purpose of facilitating convenient administration during the course of a given day (especially while a patient is away from home) is an accepted fact of medical life. The inevitable practice of comingling is made less dangerous and safer when colors are uniform. In the absence of color uniformity, patients would have to re-learn a new series of color schemes with each

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[27]Dr. Lasagna also noted a patient who suffered severe congestive heart failure as a result of confusion in color and stresses the importance of color in effective communication between doctor and patient. Id. See also Lasagna, "Placebos," 193 SCIENTIFIC AMERICAN 68-71 (1955).

dispensed medication. Worse, patients risk making an error based upon their failure to remember the latest series of colors for their respective medicines.[28]

If the brand-name companies obtain a monopoly on color, the public interest will be adversely affected by the hazards and inconvenience involved in identifying medicines as specific therapeutic agents. The testimony here shows that patients do identify their medicines in terms of color for a specific medical condition. Ultimately, color monopoly would mean that the consumer would be deprived of color as an identifying factor. We urge this Court to recognize and

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[28]See FDA CONSUMER, Oct. 1980 at 30, showing that the impact of uniform color identification, even upon professionals is a matter of critical concern. One FMA member marketed a drug known to precipitate attacks of acute glaucoma, erroneously labeled as a vitamin. Public injury was avoided only because a pharmacist noticed that the purported vitamin tablet was not in the standard orange color.

affirm that color in the field of medicine[29] is just as functional, if not more so, than the everyday color functionality which is recognized in so many other areas of commerce.[30]

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[29]Prior to the recent spate of litigation, the importance of color in drugs was never questioned:

> "The use of color in foods, drugs and cosmetics, though largely of value from the point of view of enhancing the marketability of the articles involved, is in many cases, also in the consumer interest and affirmatively desired by consumers. . . . In drugs, color additives are much used for ready identification, thus helping the pharmacist, the physician, the nurse, and the patient to avoid dangerous mistakes in choosing the wrong bottle or box." Senate Report. #795, Color Additive Amendments of 1959, Report to Accompany S.2197 (86th Cong., 1st Sess. 1959) at 11 [emphasis added].

[30]See, e.g., Plastilite Corp. v. Airlite Plastics Co., 390 F.Supp. 1141, 1148 (D.Neb.), rev'd on other grounds, 526 F.2d 1078 (8th Cir. 1975), cert. denied, 425 U.S. 938 (1976); Vitarroz Corp. v. River Brand Rice Mills, Inc., 266 F.Supp. 981, 984-985 (S.D.N.Y. 1967); Schmidt Mfg. Co. v. Sherrill Industries, Inc., 249 F.Supp. 480, 484-488 (W.D.N.C. 1965). See also 46 F.R. 32,880 (June 25, 1981) (Department of Transportation study recommending national standards of color and shape for traffic signs.).

This is not the first time that the supposed consequence of "illegal substitution" has been raised as an argument against a competitive product being marketed in a familiar and accepted color. One dramatic example involved the producers of butter, who asked Congress to require that margarine, sometimes passed off as butter, be sold only in a color other than the familiar yellow. The following description by Senator Fulbright in his ultimately successful opposition to the then-requested color monopoly virtually tracks the outline of the instant controversy:

(cont.)

See generally Hackl, "Color: A Language of Persuasion," ART PRODUCT NEWS, Vol.3, No.6 (1981); Hackl, "Hidden Meanings of Color," GRAPHIC ARTS BUYER, Vol.12, No.5 (1981); B.W. Most, "Color Scheming," AMERICAN WAY, 28 (May 1981); Dr. Max Luscher, "THE LUSHER COLOR TEST" (Pocket Books, NY 1971) (Trans. fr. German by Ian Scott). Other examples of the function of color can be found in Public Citizen v. Foreman, 631 F.2d 969, 973 (D.C.Cir. 1980) and Certified Color Mfrs. Ass'n v.

"The butter industry knows very well that consumers want their table spread whether margarine or butter, served yellow. Imagine, for example, eating green margarine or green butter, even if it were just as nutritious and tasty as yellow margarine or yellow butter. Imagine drinking red milk, even though the coloring which made it so was perfectly harmless. We are all familiar with the common practice with respect to oranges. I do not think the coloring of an orange improves it any, but, for the same kind of reason, everyone colors oranges today in the markets. It is merely a habit.

"We develop a set of food habits, which include eye appeal, as well as taste appeal, just as we develop other habits. We have been taught to like our butter served yellow and our margarine served yellow. 96 CONG.REC. S53-54 (daily ed. Jan. 4, 1950) [emphasis added].

If Ives and other brand-name companies are given the right to monopolize their color configurations, it is they who will be competing unfairly with generic drug companies. Generic products will be affected by adverse patient reactions, thus reinforcing

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(cont.)

Matthews, 543 F.2d 284, 289 and n.15 (D.C.Cir. 1976).

the brand-name companies' arguments that only the more-expensive brand-name product should be prescribed and dispensed. Surely the brand-name companies have no right to exact such a price from the American people.[31] Although, as the Parke-Davis materials point out, "trying to explain colors in words is like trying to describe music instead of playing it," Parke-Davis at 3, the record is clear that the arguments advanced by the brand-name companies are but a pretext for achieving a valuable monopoly of capsule color, which will subject the public and the generic drug industry to a significant health and economic disadvantage.

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[31] Cf. Pharmaceutical Manufacturers Ass'n v. Whelan, ___ N.Y.2d ___, No. 650 (Dec. 22, 1981).

IV. IVES' STANDARD FOR CONTRIBUTORY LIABILITY SHOULD BE REJECTED AS CONTRARY TO THE PUBLIC INTEREST

Ives' suggestion that contributory liability should be found solely because petitioners could have "reasonably anticipated" that some unlawful use might be made of their products is illogical. Mere awareness that illegal substitution exists should not be sufficient to impose contributory liability. See Coca-Cola Co. v. Snow Crest Beverages, 64 F.Supp. 980, 989 (D.Mass. 1946), aff'd, 162 F.2d 280 (1st Cir.), cert. denied, 332 U.S. 809 (1947).

The facts of this case amply show why the rule suggested by Ives should not be adopted. The alleged unlawful acts to be anticipated by petitioners in this case are claimed to have been of two types. The one primarily relied upon by Ives below relates to the "additional evidence" of mislabeling in the New York survey. Even assuming that

such "mislabeling" could be anticipated,[32] capsule color has not been shown to have any causal relationship to the acts of mislabeling by pharmacists. The so-called mislabeling occurs in instances where substitution is lawful, and the pharmacist is free to substitute a generic product, even if it were in a different color. "Mislabeling" does not derive from any ulterior motive, and capsules of a different color could be "mislabeled" just as easily as those of a similar color. How a change in color would cause a pharmacist to label differently remains a complete mystery.

The second prong of Ives' "reasonably anticipate" standard addresses the

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[32]We find totally illogical Ives' argument that petitioners in 1975 and 1976, when these products were first sold, could have anticipated that pharmacists would "mislabel" lawfully substituted generics within the meaning of a statute which had not yet been enacted, and did not take effect until April 1, 1978.

unfortunate, but inevitable, fact that petitioners and everyone else can "anticipate" that some illegal substitution occurs in the marketplace. Illegal substitution, as shown on this record, is de minimis. In a nationwide shopping of known "bad actors" at the outset of the litigation, Ives was able to unearth no more than one pharmacy in Tylertown, Mississippi, one pharmacy in Pennsylvania, and two pharmacies in New York, which illegally substituted a generic product for Cyclospasmol.[33] The Court of Appeals in Ives II found that this amount was de minimis and not probative for any purpose in this litigation. Ives II at Pet.App. 36a; 52a-53a. However, Ives elected not to conduct any further surveys for the

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[33]Ives now concedes that the Michigan shoppings failed to show illegal substitution. Rather, it argues that notice of lawful substitution may have been inadequate. Ives' description is a post hoc effort to salvage this evidence.

purpose of measuring illegal substitution.[34] A survey conducted by petitioner Premo, showed that in New York, out of 25 pharmacies shopped, there was not one single instance of illegal substitution. [Pl.Ex. 142, J.A. 375a-382a]. On this record, Ives' professed concern about illegal substitution is transparently frivolous.

Inwood requests that in view of the importance of the issue and the need for a definitive ruling this Court should not limit itself to a holding based solely upon the fact that this record shows virtually

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[34]Ives repeats the statement made by the majority below that it is surprising that it could produce as many instances as it did, given pharmacists' reluctance to admit acts of illegal substitution. Ives, however, did not obtain its de minimis evidence of illegal substitutionn by polling pharmacists for admissions of illegality. The evidence, such as it was, was obtained by presenting unsuspecting pharmacists with test prescriptions, which after dispensing, would show whether that pharmacist illegally substituted. No "admissions" were involved and Ives' decision not to conduct another survey shows that it was convinced that a second survey would be fruitless.

no illegal substitution of any consequence. As a legal principle, the fact that some illegal substitution may occur and the mere fact that a generic drug company can anticipate that it will occur to some unspecified extent, and by some unknown pharmacists, should not by itself be a predicate for contributory liability.[35]

First, the brand-name companies make virtually no effort to monitor the acts of pharmacists and to enforce the requirements of state laws against illegal substitution. Instead, they seek to place the entire burden of protecting their good will against

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[35]See e.g., Famolare, Inc. v. Melville Corp., 472 F.Supp. 738, 746 (D.Hawaii 1979), aff'd, 652 F.2d 62 (9th Cir. 1981); McCarthy, TRADEMARKS AND UNFAIR COMPETITION §25.2 at 175 (1973); cf., 3 NIMMER ON COPYRIGHT, §12.04 at 12-39 (1980) ("Certainly it would be absurd to hold the manufacturer and seller of a printing press liable as contributory infringers because the buyer uses such press for infringing purposes.")

illegal substitution upon the generic drug manufacturers.[36]

Second, there is no evidence that a change in capsule color will eliminate illegal substitution. In one recent case, there was striking evidence that a pharmacist had illegally substituted, even though the color of the drugs in question were dissimilar from the color of the respective brand-name drugs. See A.H. Robins Co. v. Medicine Chest Corp., 206 U.S.P.Q. 1015 (E.D.Mo. 1980), Transcript of Proceedings at 252-255.[37]

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[36]The problem of illegal substitution would be eliminated if brand-name companies individually wrapped or blister packed each capsule. This traditional type of "trade dress" distinguishes each capsule from its counterpart. Ives in fact markets its cyclandelate product in such a form. See Pl.Exh.13N (advertising advantages of strip packages).

[37]It is unreasonable to burden competition by granting the brand-name companies a color monopoly solely because illegal substitution, the extent of which is unknown, may be reduced, if at all, by an

Finally, the doctrine of contributory infringement should have, and has always had, an element of wrongful intent or action as its foundation for a finding of liability. See cases cited in Ives I at Pet.App. 13a. In the absence of any direct inducement, an act of suggestion, or intent to profit from the supposedly anticipated illegal conduct, the standard for contributory liability should rest on much more than just the likelihood that a portion of the marketplace will abuse a given product. Where the primary method of sale of prescription drugs is non-infringing, the fact that an indeterminable minority may violate the law should not subject a good-faith marketer to contributory liability. Compare 17 U.S.C. §271(b).

This Court should adopt the standard of contributory liability enunciated by

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(cont.)

amount which is also unknown.

Judge Friendly in Ives II. Contributory liability should not be found unless the contributor acts wrongfully by suggesting by way of promotion that the wrongful act be committed or by participating in the wrongful act by continuing to sell to a particular pharmacist whom it knows or has reason to know is engaged in unlawful activity. These two criteria for liability embody a basic fairness to the manufacturer so that it is not held liable for the intervening decision of a third party to commit a criminal offense. As noted by Justice Holmes:

> "In some cases where an ordinary article of commerce is sold nice questions may arise as to the point at which the seller becomes an accomplice in a subsequent illegal use by the buyer. It has been held that mere indifferent supposition or knowledge on the part of the seller that the buyer of spirits or liquor is contemplating such unlawful use is not enough to connect him with the possible unlawful consequences, Graves v. Johnson, 179 Mass. 55, but that if the sale was made with a view to the illegal resale the price

could not be recovered." Kalem Co. v. Harper Bros., 222 U.S. 55, 62 (1911).

The "nice questions" anticipated by Justice Holmes over seventy years ago are thus squarely presented for decision here. The unqualified mere "anticipation" rule suggested by Ives should be rejected because it threatens to permit the perpetuation of color monopolies contrary to the public interest in fully effective competition and fully effective medicine.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the ruling of the Second Circuit be reversed and that the judgment of the District Court be reinstated.

Respectfully submitted,

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IN THE

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and
PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

REPLY BRIEF OF PETITIONER PREMO PHARMACEUTICAL LABORATORIES, INC.

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REPLY BRIEF OF PETITIONER PREMO PHARMACEUTICAL LABORATORIES, INC.

Introduction

This brief is submitted by Petitioner Premo Pharmaceutical Laboratories, Inc. ("Premo") to reply to certain of the statements and propositions set forth by Respondent ("Ives") in its brief and by certain of the *amici*.

POINT I

The Argument Advanced by Ives That Compelling Petitioners to Change the Color of Their Cyclandelate Products Will Prevent Deception of the Public Is Untenable.

Ives in its brief goes to great length to urge that the only way to prevent deception of a consumer who receives Petitioners' products is by compelling Petitioners to change the color of said products. This argument is wholly illogical in that Ives does not set forth what type of deception it is referring to. The district court found that ". . . Ives failed to show that the colors indicate sponsorship or origin and have therefore acquired a secondary meaning." (Pet. App. 64a). This finding was not disturbed by the Court of Appeals in its opinion and was amply justified by the trial record before Judge Nickerson. Inasmuch as the colors of Ives' CYCLOSPASMOL product do not indicate a source of origin, one is left with the inevitable conclusion that the only function they serve for the patients who ingest them is to indicate a type of medication they are taking.

By forcing Petitioners to sell their cyclandelate products in different colors, the consumer will not think he is getting medication from a different manufacturer or source of origin since, as the trial record found, the colors do not indicate a source of origin. The only effect upon the consumer will be to make him think he is getting a different type of medication, i.e., a medication for a different therapeutic effect from that he had previously taken. If Petitioners are forced to sell cyclandelate in different colors, the only

deception to the consumer will be that he will be confused and deceived as to the true therapeutic effect of his medicine since the only function color serves to the consumer is to indentify a therapeutic activity, i.e., heart pill, water pill, pain pill, etc.

In an attempt to bolster its position that the trademark CYCLOSPASMOL identifies Ives as the source of origin, a claim is made on page 50 of Ives' brief that extensive sales of CYCLOSPASMOL and corresponding promotion establish secondary meaning.* However, the sales of Ives' product do not in any way establish secondary meaning inasmuch as the customer has no choice in the selection of

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*On p. 51 of its brief, Ives urges that its survey established that secondary meaning was shown. For the reasons advanced by the district court and for several other reasons, this argument of Ives must fail. In the survey conducted by Ives, a small number of those interviewed associated the color of Ives' product with the word "CYCLOSPASMOL". However, Ives failed to adduce any proof that these interviewees realized that CYCLOSPASMOL was a brand name or indicated a source of origin for the drug. Premo does not dispute that as to physicians and those in the health field CYCLOSPASMOL indicates Ives' drug. But there is no reason to assume that this applies at the consumer level. While the district court did not pass directly upon the merits of Ives' survey which dealt with secondary meaning, there was ample evidence before the trial court to disregard the survey in its entirety. In the first instance, Ives' survey was irrelevant because it did not purport to establish secondary meaning at the time the Petitioners entered the market with their look-alike generic cyclandelate products. It is axiomatic that "secondary meaning must have been established when the alleged infringer entered the market." *Le Sportsac, Inc.* v. *Dockside Research, Inc.*, 478 F.Supp. 602, 608 (S.D.N.Y. 1979). *See also Lucien Lelong, Inc.* v. *Lander Co.*, 164 F.2d 395, 397 (2d Cir. 1947) (secondary meaning must have been established when the defendants entered the field); *Maternally Yours* v. *Your Maternity Shop*, 234 F.2d 538, 544 (2d Cir. 1956); *Federal Glass Co.* v. *Loshin*, 224 F.2d 100, 101 (2d Cir. 1955). In addition, Ives refused to provide Petitioners with the names of the survey interviewees, which prevented Petitioners from taking suitable discovery, all in violation of the principles set forth in the *Manual for Complex Litigation*, 1 Moore's Federal Practice, Pt. 2.

the product and does not ask for Ives' drug. Still further, Ives admits on page 5 of its brief that its CYCLOSPASMOL is not advertised to the public.

Ives' concern as to how the consumer will know what drug he is getting is a bogus issue. At the time the physician prescribes the drug the physician will tell the inquiring patient what the drug is and whether or not a generic will be dispensed. This will give the patient the information he needs to have concerning what drug his doctor wishes dispensed. In addition, the patient can ask the pharmacist whether a generic is being dispensed. The suggestion by Ives that the only way the patient can tell what drug is being dispensed is by the color is simply not so, particularly in view of the fact that patients only regard color as a means of indicating a type of therapeutic activity.

POINT II

Ives' Argument Concerning Functionality Presents a One-Sided and Distorted View of the Trial Record.

Ives in its brief (pp. 11-15) discusses the question of functionality in a one-sided fashion that does not accurately reflect the testimony that was presented to the district court. It is beyond purview that Ives presented testimony to the district court that the color of the cyclandelate products was nonfunctional and Petitioners presented conflicting testimony. After hearing all of the testimony concerning this issue, Judge Nickerson found the drug colors to be functional and his finding was clearly supported by the record.

Dr. Judith Taylor, a neurologist, testified from personal experience that patients rejected taking a less expensive non-look-alike drug and that in her experience patients rely upon the appearance of a drug product as assurance that they are receiving the proper medication (JA 209a-211a).

Dr. Kent O. Shinbach, a psychiatrist who was called to testify on behalf of Petitioners, testified that patients rely on the color and appearance of capsules and tablets to assure themselves that they are receiving the proper medication. When patients receive medication with an unfamiliar appearance, "They suspect that I have written the wrong dosage. They think something is wrong and they want to know what is going on." (JA 293a).

Dr. Jerry Bloom, an internist, has prescribed CYCLOSPASMOL for his patients (Tr. 733) and testified that it is desirable from a medical standpoint for generic cyclandelate to be in the same size, shape and color as CYCLOSPASMOL (Tr. 735).

Cyclandelate is frequently prescribed for elderly patients who may exhibit symptoms of forgetfulness, disorientation, confusion, etc. and who have become accustomed to the appearance of the cyclandelate capsules (Shinbach JA 286a-290a). Such patients are frequently self-medicating, despite the aforementioned symptoms, because the degree to which these symptoms appear may not be severe or because the patient may live alone and there is no practical alternative to self-medication (Fine Tr. 45B-46B; Lehman JA 196; Taylor JA 205a-206a; Bloom JA 252a; Shinbach JA 286a-287a). Elderly patients such as those

for whom cyclandelate is prescribed frequently take more than one medication each day and may be self-medicating with different medicines (Fine JA 114a; Lehman JA 196a; Taylor JA 205a; Shinbach JA 287a). Frequently, patients commingle their medications, relying on the color to comply with their physicians' instructions regarding frequency of usage (Fine JA 115a-116a; Taylor JA 205a-207a; Bloom JA 252a-253a; Shinbach JA 288a-289a).

The colors of capsules are also frequently used by doctors and pharmacists in communicating with their patients who regularly refer to pills by colors; *e.g.*, "my red heart pill," "my blue stroke pill," etc. (Taylor JA 207a-208a; Shinbach JA 289a-290a). Obviously, such communication would be hampered and subject to confusion and misunderstanding if patients were to receive cyclandelate capsules in different color combinations whenever a prescription was refilled.

Dr. Taylor, Dr. Shinbach and Ms. Gringauz testified about their personal experiences in which the color and appearance of drug capsules played a role in assisting emergency room physicians to identify the drug consumed by the patient (Taylor JA 211a-212a; Gringauz JA 239a; Shinbach JA 296a-298a).

While Premo does not claim that color is the most significant or can be the sole clue in identifying a drug in an emergency situation, there can be no doubt that it is of some value. If generic drugs were required to be sold in colors different from their well-known brand name counterparts, this value would be lost in a plethora of confusing colors and color combinations for identical drugs.

It can thus be seen that while there was undoubtedly conflicting testimony presented to the trial court as to whether or not the drug colors were functional, the district court resolved this conflicting testimony in support of Petitioners' position.* The Court of Appeals did not even pay lip service to the district court's findings.

POINT III

Ives' Proposition That Pharmacists Are Dishonest and Cannot Be Trusted Is Unsupported by the Record.

Ives' entire theory of contributory trademark infringement boils down to one simple proposition: that pharmacists cannot be trusted to sell look-alike drugs since they will use them for illegal substitution. Ives also argues (page 23 of its brief) that the widespread instances of unlawful substitution by pharmacists has spawned many lawsuits. These statements by Ives are totally unsupported by the record. In support of its position that there have been many lawsuits with respect to illegal substitution since 1924, when the *Warner* case was decided by this Court, Ives has only been able to identify a handful of cases. Ives' position that pharmacists inherently cannot be trusted and engage in widespread acts of illegal substi-

* The argument advanced by the Pharmaceutical Manufacturers' Association that the question of functionality is a matter of law is frivolous. The fact that different courts have reached different conclusions with respect to this question merely highlights the significance that should be attributed to the district court's careful evaluation of all relevant testimony. In *Ives II*, Judge Friendly specifically held that functionality was a factual question, stating: "The case for functionality thus depends on the evidence proffered by defendants that copying whatever colors Ives had chosen served a number of utilitarian purposes. . . ." (Pet. App. 50a).

tution is at variance with the testimony of its witness, Brendon Lawlor, a practicing pharmacist and President of the New York State Pharmaceutical Society, who testified that, based upon his experience, there was little evidence of illegal substitution by pharmacists* (JA 182a).

In any event, it is clear that for the reasons enumerated by the district court the copying of colors serves a beneficial purpose and, to the extent that any licensed professional may illegally substitute, he is subject to disciplinary provisions by his licensing board.

Ives in its brief attempts to bolster its position that there is widespread illegal substitution by referring to the March 13, 1979 report of the Attorney General of the State of New York (page 11 of its brief). Specifically, Ives urges that the report shows nearly one-quarter of the pharmacists in New York violate the generic drug law in filling prescriptions and do not pass full savings along to the consumer. This statement by Ives is out of context. What the report held was that the pharmacists are not making required substitutions when directed to do so by the prescribing physicians and as such the pharmacist is not passing along to the consumer the lower price of the generic drug.

Ives on page 27 states that there are over 3,000 pharmacies in the State of New York, implying that it should not

* The statement in the footnote on page 36 of Ives' brief that the potential for deception and confusion is shown by Ms. Gringauz filling Medicaid brand name prescriptions with generic drugs is disingenuous. Ms. Gringauz testified that in the hospital where she is employed she has prior written consent from every doctor on the staff giving her the option to dispense generically when filling a prescription (Tr. 715).

be expected to sue each one. This statement by Ives is outrageous in its attempt to implicate all the pharmacists in New York State as being involved in illegal substitution. As Ives has demonstrated in this lawsuit, it is an easy matter to locate those pharmacies who are engaged in mislabelling generic look-alikes and there is no reason why it cannot initiate lawsuits against those pharmacies as it did in this case. The argument that there are 3,000 pharmacies should not be a basis for allowing Ives to use its word trademark CYCLOSPASMOL to enjoin Petitioners from selling their look-alike products when this Court has traditionally held that colors cannot be protected.*

POINT IV

Ives Is Incorrect When It Urges That Petitioners Can Compete Equally as Well by Selling Their Drug Products in Different Colors.

The very intensity with which Ives has prosecuted this suit and with which the large drug manufacturers have attempted to preserve their monopoly on drug colors belies the claim that Petitioners could compete equally as well in different colors. Certainly no one believes that Ives has prosecuted this suit because of an altruistic concern for the consumer. The reason Ives has prosecuted this suit is that Petitioners are able to compete more effectively by selling their generic products as look-alikes and the reason

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* *A. Leschen & Sons Rope Co.* v. *Broderick*, 201 U.S. 166, 170-71 (1906); *American Basketball Assoc.* v. *A.M.F. Voit, Inc.*, 358 F. Supp. 981, 985 (S.D.N.Y.), *aff'd without opinion*, 487 F.2d 1393 (2d Cir. 1973), *cert. denied*, 416 U.S. 986 (1974); *Plastilite Corp.* v. *Kassnar Imports*, 508 F.2d 824, 826 (C.C.P.A. 1975); *Diamond Match Co.* v. *Saginaw Match Co.*, 142 Fed. 727 (6th Cir. 1906); *Campbell Soup Co.* v. *Armour & Co.*, 175 F.2d 795 (3d Cir. 1949), *cert. denied*, 338 U.S. 847 (1949).

for this is quite simple. The consumer does not identify the color of the product with a source of origin but only with a therapeutic effect. Thus, a patient who has taken a drug during the life of the patent in one color and uses the color to identify the drug as his heart pill, upon receiving a drug with the same chemistry in a different color, will only assume he is not receiving a heart pill but a drug having a different therapeutic effect. This is why Petitioners cannot compete as effectively by selling non-look-alikes.

Ives in its brief argues the fact that SK&F sold a line of generics that were not look-alikes and therefore Petitioners should follow suit. However, testimony with respect to the SK&F line by the Chief Pharmacist of a New York hospital showed that some patients refused to take an SK&F drug thinking it was the wrong medication (JA 276a-278a).

POINT V

Ives' Argument Concerning the *Sears* and *Compco* Cases Is Disingenuous.

The argument advanced by Ives on page 39 of its brief concerning *Sears/Compco* is distorted. If this Court were to follow Ives' interpretation of *Sears* and *Compco,* then the pole lamp of the *Sears* case and the lighting fixture of the *Compco* case could not have been copied with impunity as this Court held.

As this Court noted in the *Sears* case:

> ". . . because of the federal patent laws a State may not, when the article is unpatented and uncopyrighted,

prohibit the copying of the article itself or award damages for such copying."

(376 U.S. 232-33).

The import of the *Sears* and *Compco* cases is clear. States may not use their unfair competition laws to give protection to that which is not protectable under the patent, trademark and copyright statutes. Ives in its argument concerning §43(a) of the Lanham Act is, in effect, trying to circumvent the rationale of the *Sears* and *Compco* cases by urging that §43(a) of the Lanham Act can be used as a basis for protection for that which otherwise would not be protectable under the patent, trademark or copyright statutes.

As Premo has pointed out on page 21 of its main brief, the use of §43(a) of the Lanham Act to eviscerate the holdings of the *Sears* and *Compco* cases is improper and this Court is again urged to rule on the question of whether §43(a) of the Lanham Act can be used to prevent copying the appearance of an article when such an appearance is not protectable under the patent, trademark or copyright laws. To allow §43(a) to be used as Ives suggests runs counter to Article II, Section 8, Clause 8 of the Constitution which provides that protection can only be had where such protection would promote the progress of science and the useful arts by authors and inventors. Under no circumstances could one consider the selection of a blue color or a blue and red color combination to be an invention or to be the work of an author.

POINT VI

The Argument by the PMA That Look-Alike Marketing Frustrates Consumer Choice Is Devoid of Merit.

In the PMA brief (page 20), an argument is made that look-alike marketing frustrates consumer choice. This argument totally misconstrues the nature of dispensing pharmaceutical drugs. Under New York State law [§6810(6)(a) of the Education Law], a prescription form must conspicuously state that the prescription will be filled generically unless the physician indicates otherwise. Two lines are then provided, one over the words "Substitution permissible" and the other over the words "Dispense as written".

Unless the physician otherwise directs, the pharmacist making a substitution must indicate on the label the name and strength of the drug and its manufacturer and where the brand name drug is dispensed, §6815(2)(j) requires the pharmacist to affix the brand name. Thus, it can be seen that the physician determines whether the patient receives a generic drug or a brand drug. The pharmacist will dispense a generic drug if the "Substitution permissible" line is signed by the physician and otherwise a brand drug. However, under New York State law the patient has no choice, once the prescription blank has been filled out, as to which drug is dispensed to him.

The argument by the PMA concerning consumer choice simply represents a misunderstanding of how prescription drugs are sold. They are not sold in New York by a consumer going into a drugstore and making a selection between a brand name or generic drug. When the patient comes into the store with a prescription he has no say in whether the pharmacist fills the prescription with a

branded drug or a generic product. While the freedom of choice argument advanced by the PMA might under some circumstances have relevancy where a consumer selects goods from a store shelf, it has no bearing whatsoever insofar as prescription drugs are concerned.

POINT VII

The Suggestion by the PMA That the Look-Alike Generic Drug Products May Endanger Public Health Is Not Supported by the Record.

The PMA in its brief urges on page 17 that look-alike drugs may endanger public health. This argument by the PMA has no relevancy to the case at hand. Ives has never once asserted any proof whatsoever that Petitioners' products have any different effect on the consumer than its product. Throughout this case all parties have treated the products of the Petitioners and Ives as being equivalent in all respects.

POINT VIII

The Suggestion by the PMA That Certiorari Was Improvidently Granted Is Frivolous.

The PMA's suggestion that the Court should dismiss the writ of certiorari as improvidently granted is not supported by fact or law. In taking a position which not even Ives has urged, the PMA has based its argument, set forth on pages 8, *et seq.* of its brief, on two premises: first, that the present case is a look-alike case in which the Court of Appeals only ruled on the contributory infringement claim, and second, that the parties have not briefed the §43(a) claim.*

* It is beyond purview that this Court has jurisdiction under 28 U.S.C. §1254(1).

The PMA's first argument is that since most look-alike cases are prosecuted under §43(a) and as the Court of Appeals did not rule on Ives' §43(a) claim, the "look-alike" issue is not properly before this Court. This argument totally ignores that there is a significant issue of contributory infringement before the Court that disposed of the look-alike issue and that Petitioners are under an injunction from selling their look-alike cyclandelate products. The look-alike issue now before this Court is in the context of a contributory trademark infringement claim which has been directly passed upon by the Second Circuit.

The §43(a) claim has been briefed by several of the parties (including Ives and Premo), discussed by the district court and Judge Friendly in *Ives II*, and Judge Mulligan in his dissent in *Ives IV*, and the principles that this Court lays down with respect to *Sears/Compco* and other questions concerning this case will definitely provide guidance to future courts concerning the application of §43(a) to look-alike cases.

Conclusion

The decision of the Court of Appeals under review should be reversed.

Respectfully submitted,

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Nos. 80-2182, 81-11

In the Supreme Court of the United States

October Term, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES, INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Petitioners,

vs.

IVES LABORATORIES, INC.,
Respondent.

BRIEF OF AMICUS CURIAE AMERICAN ACADEMY OF FAMILY PHYSICIANS IN SUPPORT OF RESPONDENT

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vs.

IVES LABORATORIES, INC.,
Respondent.

BRIEF OF AMICUS CURIAE AMERICAN ACADEMY OF FAMILY PHYSICIANS IN SUPPORT OF RESPONDENT

INTEREST OF THE AMICUS CURIAE

The question before the Court is whether manufacturers and distributors of prescription drugs are liable for contributory infringement of a registered trademark when they package and distribute a generic drug identical in appearance to the brand name drug for which theirs is generic. Petitioners' briefs present to the Court the position of the generic drug manufacturers and distributors. Respondent's brief presents to the Court the position of the brand name drug manufacturer. One very important position has yet to be presented to the Court - that of the

physician whose task is to provide medical care to his patients.

Because of the complex and technical bases on which prescribing decisions are made, patients as such do not possess the medical knowledge to assess and present their own true needs in this area. The medical needs of the patients are the business of the medical profession. Accordingly, the most significant spokesman for the needs of the patient relevant to the inquiry before the Court is the patient's own physician.

The American Academy of Family Physicians (hereinafter called the "Academy") is the professional society of physicians specializing in the field of family medicine. It is the largest medical specialty society in the world. As of October 31, 1981, the Academy had 51,147 members.

One purpose for which the Academy was organized is to ensure that the people of America receive excellence in health care. In its most recent fiscal year ended May 31, 1981, Academy members contributed $3,132,778 in dues payments to the Academy to assist in the furtherance of overall goals of their profession. From these funds and other sources developed by the Academy, the Academy in that year expended a total of $11,400,620 in various projects designed to promote and maintain high standards of family and general practice of medicine and surgery; to encourage and assist young men and women in preparing, qualifying and establishing themselves in family and general practice; to preserve the right of family physicians to engage in medical and surgical procedures for which they are qualified by training and experience; to assist in providing post-graduate study courses for family physicians and to encourage and assist practicing physicians to participate in such training; to promote the general betterment of public health and to preserve to patients their

right of free choice of their physician; and to engage in responsible public advocacy in connection with issues relating to the provision of medical care for the public.

The Academy is a national body with 54 chartered constituent chapters in all 50 states, the District of Columbia, Puerto Rico, the Virgin Islands and the uniformed services. The Academy is organized structurally to provide representative government at the national level for all its members. To this end, each chartered constituent chapter selects two representatives to a Congress of Delegates, which meets annually and which is the supreme authority within the Academy for determining the Academy's position on any issue. The Congress of Delegates selects members of a Board of Directors which has authority to govern the Academy and to determine its affairs between meetings of the full Congress. Accordingly, policy positions of the Academy, of which some are hereinafter quoted, constitute the collective determination of the full national membership of the Academy as expressed through its representatives at its Congress of Delegates.

This brief for this *Amicus Curiae* discusses the following points in support of Respondent's position:

1. The need of the physician, in treating a patient, to be able to know in appropriate circumstances the specific products, including the brand of medications, his patient is actually receiving in response to the prescriptions issued by the physician.

2. The patient's right to know and to be able to determine whether his prescription has been filled with a brand name drug or its generic substitute and, where the latter is appropriate, whether he has received the benefits of any cost savings.

SUMMARY OF THE ARGUMENT

To provide effective medical care for a patient, a physician must have the right to prescribe specific medicines for his patient and where appropriate to restrict the medicines dispensed by a pharmacist to particular prescribed brands of medications. Such right of the physician to control what is dispensed under his prescriptions has been acknowledged even in laws otherwise permitting a pharmacist to make substitutions in prescriptions where the physician has not exercised his right to restrict the pharmacist to particular brands.

Unauthorized substitutions in prescriptions, intentional or not, subvert the physician's medical care of his patient. Marketing practices which permit or encourage the possibility of confusion between different brands of a given medication create conditions in which unauthorized substitutions may be undetected, because a patient will not be put on his inquiry to determine what he has received and will accordingly feel no occasion to raise any questions with his physician to ascertain what the patient has received. Unauthorized substitutions which are not known to the patient or his doctor could endanger the health of the patient because the doctor may be led to improper diagnoses either of the patient's conditions or of the efficacy of a particular medication in treating that condition.

Laws permitting authorized substitutions are intended to secure cost savings for patients. When a prescription is filled by substitution, whether such substitution is authorized or not, if the patient has no knowledge of the substitution, he may not know he is entitled to cost benefits and may therefore not receive the cost savings the laws intended for him. The possibility that a substitution may be made without the patient's knowledge, even though

authorized by law, is heightened by trade or marketing practices which are intended to make different products similar in appearance and which accordingly provide a patient no visual perception that a substitution has been made.

Requiring different brands of a medication to be different in appearance eliminates at least one set of possibilities of confusion both in the medical care of a patient and in the patient's awareness of his right to financial savings where appropriate. Requiring such differences in appearances will aid physicians in providing quality medical care without countervailing detriments to physician convenience and without significant cost to manufacturers.

ARGUMENT

I. Optimal Medical Treatment of a Patient Requires That the Physician Be Able to Direct the Medications to Be Dispensed to the Patient, and Practices Which Permit or Encourage Substitutions in Prescriptions Without the Knowledge of Either the Patient or His Physician Are Not in the Best Interests of Quality Medical Care and May Endanger the Patient's Health.

Virtually every drug which has been promoted under a registered trademark in fact has three different names:

1. The chemical name which describes the chemical structure or composition of the drug.
2. The generic name which describes the chemical class to which the drug belongs.

3. The brand name which is the registered trademark of the manufacturer and which describes the source of the drug.[1]

The brand name drug is usually more expensive than the generic drug of the same chemical class. The brand name drug manufacturers have invested great sums in clinical research and development, in the drug approval process, and in marketing of the drug. The generic drug manufacturer does little, if any, pharmaceutical product research and does not incur costs associated with introducing a new product.

Virtually all states and the District of Columbia have enacted Generic Drug Substitution laws which permit the pharmacist to substitute, under certain specified conditions, a generic drug for a brand name drug which has been prescribed. The general purpose of making the drug available in its generic form is to permit the consumer to receive the lowest cost form of the drug. In the ideal situation, cost savings realized by substituting a generic drug for a brand name drug will be passed on to the consumer.

The prescription drug market is very different from a classic free market. Most consumers of prescription drugs lack the knowledge to deal effectively with the supplier of drugs. The consumer receives his drug packaged in an anonymous bottle bearing only the pharmacist's label. He is unable to determine whether the proper drug is being dispensed and must rely on the ability and the honesty of his pharmacist.[2]

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1. Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Kentucky Law Journal 384, 388 (1978-1979).

2. See Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Kentucky Law Journal 384 (1978-1979) which describes some of the drug legislation that has been enacted to protect the consumer in this situation.

Courts have recognized that prescribing drugs is a specialized task based upon the sophisticated diagnostic skills of a physician. In deciding which drug to prescribe to the patient, the physician must consider the nature of the ailment and the identity of his patient. If more than one type of drug is available to treat the ailment, the physician must select the drug which he believes is most appropriate and in which he has the most confidence based upon his experience.[3]

A brand name drug and its generic substitute may be chemically equivalent without being therapeutically equivalent. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 963-965 (D.N.J. 1981). The Drug Bioequivalence Study Panel, charged by the Office of Technology Assessment (an agency of which the Board of Directors consisted of Senators and Representatives and the Chairman of which in 1974 was Senator Edward M. Kennedy) "to examine the relationships between the chemical and therapeutic equivalence of drug products," stated in its report to Congress dated July 15, 1974:

> "It was clear to us from the outset that certain chemically equivalent drug products have produced clinically important and measurable differences in therapeutic effect and that these differences were the result of differences in bioavailability."[4]

Each finished dosage form is composed of active and inert ingredients that may undergo a complicated manufacturing process. Two drugs that contain identical active chemical ingredients may not have the same effectiveness

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3. *Hoffman La Roche, Inc. v. Premo Pharmaceutical Laboratories, Inc.*, 210 USPQ 374, 383 (D.N.J. 1980).

4. *Drug Bioequivalence*, A Report of the Office of Technology Assessment Drug Bioequivalence Study Panel (U.S. Govt. Printing Office, 1974), p. 5.

in treating an ailment because of small differences in their inert ingredients or in manufacturing techniques. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 963-965 (D.N.J. 1981).

For example, the dissolution rate of the brand name drug and its generic substitute may be different so that one drug may dissolve and begin working more quickly than the other. Such differences in the dissolution rate could be critical in situations where the speed of the drug is important. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 982-985 (D.N.J. 1981). Sometimes a physician will prescribe a particular brand name drug because it has a special feature which the chemically equivalent generic drug does not have or because the carrying agent of the brand name or generic drug is not compatible with the other drugs that the patient is taking.[5]

At least as early as 1967 the Academy's Congress of Delegates adopted a formal policy position for the Academy which incorporated significant recognition of the need for a physician to have the freedom of choice to prescribe a generic drug or a brand name drug, as the physician might determine most appropriate for the circumstances.[6]

Consistent with all of the foregoing, the Academy's Congress of Delegates adopted the following formal policy at its session in 1970:

> "The Academy contends chemical equivalency does not equate with therapeutic equivalency: that the effectiveness and method of use of drug products is determined by clinical impressions of the medical pro-

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5. Willig, "The Prosubstitution Trend in Modern Pharmacy Law," 6:1 Journal of Law Reform 1, 19-21 (Fall 1972).

6. American Academy of Family Physicians, *1981-1982 Ready Reference Guide, Academy Policy on Key Health Issues* 16 (1981).

fession, based on their actual determination of what the drug product will do for their patients; and that the clinical training and experience of the physician has equipped him to be the most effective therapeutist in the patient's best interests. The Academy believes that, because the physician is responsible for total care of those patients who come under his supervision, the physician should determine the medical product to be prescribed for his patient and that the pharmacist should not be allowed to fill the prescription with a product not intended by the prescribing physician.[7]

The need for a physician to have control over the medication that his patient receives is acknowledged even in the most far-reaching of the various state statutes which have been adopted to encourage generic substitution of drugs. Even those statutes which in effect do not merely permit but require a pharmacist to make such generic substitutions whenever feasible retain the specific right for a physician to indicate on his prescription that the pharmacist must dispense only the specifically prescribed drug or, where so limited, the specifically prescribed brand of drug.[8]

Given the need in appropriate circumstances for the physician to have control over the brand of medicine he prescribes, combined with the fact that the patient receives the actual medicine not from his physician but from a pharmacist in a separate location, whatever conditions would assist a patient in detecting a substitution in his prescription will be to that patient's medical benefit. If safeguards can be devised to alert a patient visually to a sub-

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7. American Academy of Family Physicians, *1981-1982 Ready Reference Guide, Academy Policy on Key Health Issues* 14 (1981).

8. Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Kentucky Law Journal 384, 397 (1978-1979).

stitution, the patient can be on his inquiry to let his doctor know of such substitution.

Conversely, however, if the patient can be fooled by deceptively similar appearances of differing brands of medicines, then perforce the patient will never have occasion to raise any question with his doctor, and the physician will never know that the patient may be receiving a different brand of drug from that prescribed.

The use of differing colors on different products would at least make it more likely that a patient might notice an unauthorized substitution. However, apparently it is precisely the notice by a patient that the Petitioners' products are not those of the Respondent which the Petitioners fear and which the Petitioners are trying to avoid by the use of colors of identical shade and description with those of the Respondent's product.

With the patient's welfare at stake, and with the physician's need to have every possible assistance in treating the medical needs of his patient, and given the impossibility of scientific treatment if the patient receives, without the knowledge of the physician, a different brand of medicine when a specific brand has been prescribed, physicians can only be amazed that manufacturers of drugs would not affirmatively desire to differentiate their products for distinctive identification.

However, Petitioners contend that they need to use the same colors for their products as those used by the Respondent in order to compete commercially with the Respondent.

Perhaps the shortest and quickest answer is that the record herein shows at least one manufacturer has indeed found it possible to market the generic product at issue in this case in capsules of a different color from those of the

Respondent. *Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538, 545 (2nd Cir. 1981).

Even if so practical an answer were not available, the Academy would respectfully suggest that not even so vital a principle as free commercial competition is unlimited. Surely competition is not so sacred an idol that the physical welfare of patients must be sacrificed upon its altar.

Indeed, is it truly "competition" we are discussing, when the privilege sought is not the right to persuade a consumer to purchase a manufacturer's product in preference to that of his competitors, but rather a right to deceive the consumer into thinking it is the competitor's product he is buying? Certainly this type of "competition" has not been favored by the courts. As the Court in *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3rd Cir. 1980), succinctly stated:

> ". . . Premo [argued] . . . that it could compete more effectively in the diuretic market if it could use the same maroon and white capsule color adopted by SKF for DYAZIDE. Probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound, or feel of equity." *Id.* at 1067.

Clearly something is wrong with "competition" the goal of which is to deceive patients into thinking they are getting a product which they are not. Even more to the point so far as the Academy is concerned, such "competition" may be dangerous to the physical welfare of the patient: if the patient does not know he is getting a different brand of product from the one actually prescribed for him, the doctor may never know that the patient is not receiving the brand of medicine prescribed. The physician may therefore reach inaccurate decisions because the in-

formation provided to him is inaccurate. *U.S. v. Premo Pharmaceutical Laboratories, Inc.*, 511 F.Supp. 958, 985 (D.N.J. 1981).

Given the need of the physician to know and in appropriate cases to be able to control the brand of medicine dispensed to his patient, the conclusion of the opinion below provides an elemental, common-sense balancing of such competitive rights as may be involved with the requirements for effective medical treatment of patients:

> "The simplest way to reduce illegal substitution and mislabeling is to require that cyclandelate be sold in capsules which do not resemble those used for CYCLOSPASMOL. This would alert the patient to the possibility that he has been given cyclandelate when his doctor specifically prescribed CYCLOSPASMOL, as well as put him on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received. Such a change could be made by appellees without any appreciable difficulty or expense." *Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538, 545 (2nd Cir. 1981).

Various materials before this Court have argued that physicians would refrain from prescribing the Petitioners' products if the Petitioners are required to market their products in colors different from those used by the Respondent.[9] Such assertions have gone so far as to suggest that a physician will prescribe a given brand because of its color. These assertions are unsupported, but represent so astounding a theory of the practice of medicine that the

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9. See, for example, Brief of Petitioner Inwood Laboratories, Inc. 50; Brief of *Amicus Curiae* Generic Pharmaceutical Manufacturers Association 25; and Brief of *Amici Curiae* American Association of Retired Persons and the National Retired Teachers Association 5.

Academy believes they should not go unanswered. While the Academy cannot introduce evidence herein, the Academy, as the largest medical specialty society in the world, states its unequivocal belief that no responsible physician bases his prescription for his patient upon the color of the capsules; that no responsible physician would refrain from prescribing a medicine, or a particular brand thereof, which that physician felt best for his patient merely to conserve the physician's own time; and that physicians have not in fact encountered significant problems in securing patient compliance with prescriptions because of color, but if a patient should question the color of his prescription, the physician would be ready and able to explain the appropriateness of the particular prescription (either brand or generic, as the case might be).

II. The Patient Has the Right to Know and Be Able to Determine Whether His Prescription Has Been Filled With the Brand Name Drug or a Generic Substitute, Not Only As a Matter of Elemental Fairness but Also to Enable Him to Determine Whether He Is Accorded Benefits of Cost Savings Where His Physician Has Permitted Generic Substitutions.

There are several reasons why a patient has the right to know what medicine is being dispensed to him. Most importantly, his basic human right to receive medical treatment certainly contains within it the right to know that the brand of medicine which he receives is that which has been prescribed for him, or at the least to know if there is any difference. The essential reason for this right of the patient is to ensure that the patient receives the medical treatment his physician intended, as discussed in the preceding section of this brief.

Drug substitution laws have been developed for a further purpose which is intended to be beneficial to the patient. The general purpose of such laws is to secure cost savings which, in the ideal situation, will be passed on to the consumer. The Academy is in full and indeed active accord with the goal of reducing the cost to patients of medical treatment. The Academy sponsors, co-sponsors or otherwise supports numerous study and research projects each year the goal of which is to find ways of reducing costs of medical care without unsatisfactorily reducing the quality of that care. As previously noted herein, official Academy policy adopted in 1967 referred specifically to the propriety of a generic prescription where appropriate to a patient's medical condition.[10]

Obviously, however, if a patient can be fooled into believing that he has received a higher priced product because the capsules dispensed to him look just like the higher priced product, the patient becomes a very easy mark for the unscrupulous pharmacist (and indeed simply for the inadvertent pharmacist who may also be misled by the similarity in appearance into making innocent mistakes). Such a patient may be denied the cost savings to which he is entitled without ever knowing the difference.

The Petitioners' argument that the color of the capsule somehow performs a "function" rests at bottom on the goal of deceiving the patient. In essence, Petitioners argue that if a patient knows he is not getting the brand of medicine prescribed for him, he may develop anxiety. Petitioners' "cure" for such anxiety is to use similar colors so that a substituted brand will look just like the prescribed one. Thus the patient will think he is getting a product

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10. American Academy of Family Physicians, *1981-1982 Ready Reference Guide, Academy Policy on Key Health Issues* 16 (1981)

he really is not getting and, in his blissful ignorance, he will not develop anxiety. Wholly apart from the medical dangers and indeed the sheer arrogance of such an argument, the immediate point is that a patient receiving such a substitution, of which he is deliberately kept unknowing so that he will not develop "anxiety," will by that reason not know to complain when he is charged full price for the substituted product.

It is not necessary to hypothesize most pharmacists as dishonest or careless in order to condemn the conditions that make such results possible. The record in this case contains ample instances where improper substitutions have been discovered to show that the possibility of such substitutions is not merely a figment of an active imagination. Whether such results have occurred honestly or dishonestly, their net result to the patient is the same: not only is the patient exposed to the risk of improper medical treatment, but he may also be denied the financial benefits which the drug substitution laws were supposed to obtain for him.

The courts below have provided a practical answer. Judge Friendly, on the original appeal to the Second Circuit, noted that "an endless number of color combinations was available to the defendants." *Ives Laboratories, Inc. v. Darby Drug Co.*, 601 F.2d 631, 643 (2nd Cir. 1979). Judge Mansfield, writing for the Court of Appeals the opinion with respect to which this writ was granted, noted that by simply using capsules which did not resemble those used by the Respondents, the Petitioners could, "without any appreciable difficulty or expense" put a patient "on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received." *Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F.2d 538, 545 (2nd Cir. 1981).

CONCLUSION

The Academy has been organized and exists for the primary purpose of enhancing the quality of medical care. It is concerned whenever practices are encouraged which endanger the adequacy of medical treatment. For the reasons stated, the Academy believes that permitting different products intended for a given medical condition to be unnecessarily similar in appearance creates the possibility of deficiencies in medical treatment and in some circumstances endangers the patient's welfare. Therefore, the Academy respectfully requests that the judgment of the Court of Appeals herein be affirmed.

Respectfully submitted,

GERALD W. GORMAN
(Counsel of Record)
DIETRICH, DAVIS, DICUS, ROWLANDS & SCHMITT
1700 City Center Square
1100 Main Street
Kansas City, Missouri 64105
(816) 221-3420
Attorneys for American Academy of Family Physicians

Of Counsel:
CAROL A. WESTRICH

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of December, 1981, three copies of the Brief of *Amicus Curiae* American Academy of Family Physicians In Support of Respondent were served by United States mail with first-class postage prepaid on each of the following:

1. Marie V. Driscoll, Esquire
   Cooper, Dunham, Clark, Griffin & Moran
   Attorneys for Respondent Ives Laboratories, Inc.
   30 Rockefeller Plaza
   New York, New York 10112

2. Robert V. Marrow, Esquire
   Salon, Marrow, Dyckman & Kellman
   Attorneys for Petitioners Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.
   41 East 42nd Street
   New York, New York 10017

3. Milton A. Bass, Esquire
   Bass, Ullman & Lustigman
   Attorneys for Petitioner Inwood Laboratories, Inc.
   747 Third Avenue
   New York, New York 10017

4. Peter T. Cobrin, Esquire
   Kirschstein, Kirschstein, Ottinger & Cobrin, P.C.
   Attorneys for Petitioner Premo Pharmaceutical Laboratories, Inc.
   666 Fifth Avenue
   New York, New York 10103

I further certify that all parties required to be served have been served.

/s/ GERALD W. GORMAN
GERALD W. GORMAN
(Counsel of Record)
DIETRICH, DAVIS, DICUS, ROWLANDS
& SCHMITT
1700 City Center Square
1100 Main Street
Kansas City, Missouri 64105
(816) 221-3420
Attorneys for American Academy of Family Physicians

EXHIBIT A

[Letterhead of Cooper, Dunham,
Clark, Griffin & Moran]

November 27, 1981

Gerald W. Gorman, Esq.
Dietrich, Davis, Dicus, Rowlands & Schmitt
1700 City Center Square
1100 Main Street
Kansas City, Missouri 64105

Re: Inwood Laboratories, Inc. et al v. Ives
Laboratories, Inc. and
Darby Drug Co., Inc. et al v. Ives
Laboratories, Inc.
Nos. 80-2182 and 81-11

Dear Gerald:

This is to confirm that Respondent, Ives Laboratories, Inc. consents to the filing of a brief amicus curiae in this case by the American Academy of Family Physicians.

Sincerely yours,

/s/ Marie Driscoll
Marie V. Driscoll
Attorney for Respondent

MVD:jt

EXHIBIT B-1

[Letterhead of Dietrich, Davis,
Dicus, Rowlands & Schmitt]

December 3, 1981

Mr. Milton A. Bass, Esquire
Bass, Ullman & Lustigman
747 Third Avenue
New York, New York 10017

Re: Darby Drug Company, Inc., Inwood Laboratories, Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Company, Inc. vs. Ives Laboratories, Inc.

Dear Mr. Bass:

In accordance with Rule 36 of the Rules of the Supreme Court of the United States, we respectfully request your written consent to our filing of a brief amicus curiae in the above-captioned matter on behalf of the American Academy of Family Physicians.

Please acknowledge your consent by signing this letter at the space indicated below and returning the same via the enclosed addressed envelope.

We appreciate your cooperation in this matter.

Very truly yours,

/s/ Gerald W. Gorman
Gerald W. Gorman

GWG:cle

Petitioner Inwood Laboratories, Inc. consents to the filing of the brief amicus curiae in the captioned matter on behalf of the American Academy of Family Physicians.

DATE: 12/7/81

/s/ Milton A. Bass
Milton A. Bass, Esquire
Attorney for Petitioner
Inwood Laboratories, Inc.

EXHIBIT B-2

[Letterhead of Dietrich, Davis,
Dicus, Rowlands & Schmitt]

December 3, 1981

Mr. Peter T. Cobrin, Esquire
Kirschstein, Kirschstein, Ottinger & Cobrin, P.C.
666 Fifth Avenue
New York, New York 10103

Re: Darby Drug Company, Inc., Inwood Laboratories, Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Company, Inc. vs. Ives Laboratories, Inc.

Dear Mr. Cobrin:

In accordance with Rule 36 of the Rules of the Supreme Court of the United States, we respectfully request your written consent to our filing of a brief amicus curiae in the above-captioned matter on behalf of the American Academy of Family Physicians.

Please acknowledge your consent by signing this letter at the space indicated below and returning the same via the enclosed addressed envelope.

We appreciate your cooperation in this matter.

Very truly yours,

/s/ Gerald W. Gorman
Gerald W. Gorman

GWG:cle

Petitioner Premo Pharmaceutical Laboratories, Inc. consents to the filing of the brief amicus curiae in the captioned matter on behalf of the American Academy of Family Physicians.

Date: 12/8/81

/s/ Peter T. Cobrin
Peter T. Cobrin, Esquire
Attorney for Petitioner Premo
Pharmaceutical Laboratories,
Inc.

EXHIBIT B-3

[Letterhead of Dietrich, Davis,
Dicus, Rowlands & Schmitt]

December 3, 1981

Mr. Robert V. Marrow, Esquire
Salon, Marrow, Dyckman & Kellman
41 East 42nd Street
New York, New York 10017

Re: Darby Drug Company, Inc., Inwood Laboratories, Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Company, Inc. vs. Ives Laboratories, Inc.

Dear Mr. Marrow:

In accordance with Rule 36 of the Rules of the Supreme Court of the United States, we respectfully request your written consent to our filing of a brief amicus curiae in the above-captioned matter on behalf of the American Academy of Family Physicians.

Please acknowledge your consent by signing this letter at the space indicated below and returning the same via the enclosed addressed envelope.

We appreciate your cooperation in this matter.

Very truly yours,

/s/ Gerald W. Gorman
Gerald W. Gorman

GWG:cle

Petitioners Darby Drug Company, Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Company, Inc. consent to the filing of the brief amicus curiae in the captioned matter on behalf of the American Academy of Family Physicians.

Date: 12/8/81

/s/ Robert V. Marrow
Robert V. Marrow, Esquire
Attorney for Petitioners.

No. 80-2182

Supreme Court, U.S.
FILED
NOV 30 1981
ALEXANDER L. STEVAS,
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

DARBY DRUG CO., INC., INWOOD LABORATORIES, INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

ON A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF *AMICI CURIAE* OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS AND THE NATIONAL RETIRED TEACHERS ASSOCIATION IN SUPPORT OF THE PETITIONERS

MILLER, SINGER, MICHAELSON & RAIVES, P.C.
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Attorneys for Amici Curiae

ALFRED MILLER,
Counsel of Record

RICHARD C. EBELING,
Of Counsel

QUESTIONS PRESENTED

1. Whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement?

2. Whether Section 32 of the Lanham Act (15 U.S.C. § 1114) grants a trademark owner monopoly rights in the color of its product?

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

No. 80-2182

DARBY DRUG CO., INC., INWOOD LABORATORIES, INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

ON A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF *AMICI CURIAE* OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS AND THE NATIONAL RETIRED TEACHERS ASSOCIATION IN SUPPORT OF THE PETITIONERS

STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Association of Retired Persons (AARP) and the National Retired Teachers Association (NRTA) are affiliated and jointly administered not-for-profit membership corporations of more than 12,500,000 persons over the age of 55.

This figure represents approximately one out of four people over the age of 55 nationwide, the largest organized group of older Americans in the country. Among the purposes of AARP are: to enhance the quality of life for older persons; to promote independence, dignity and purpose for older persons; to lead in determining the role and place of older persons in society; and to improve the image of aging. Among the purposes of NRTA are: to promote the social welfare and needs of retired teachers, administrators and all other persons eligible for membership, to improve the quality of life for retired teachers, school administrators, and all older Americans, to the end that aging is achieved with independence, dignity and purpose; and to sponsor research on physical, psychological, social, economic and other aspects of aging.

As retired persons, many members of AARP and NRTA live on relatively fixed incomes and, because of their advanced age, many also depend on regular or frequent administration of pharmaceuticals for their continued well being. Because of the need to contain the already high and rapidly increasing cost of health care, including expenses for drugs, this case is especially critical to the health and welfare of AARP and NRTA members and of all older Americans.[1]

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1. The elderly spend a far greater amount per capita on health care each year than younger persons. In 1979, the average annual health care expenditure for persons over 65 was $2,257 or 3½ times the average amount expended by persons under 65. While older Americans comprise only 11.2% of the population, they spend 29% of the total nationwide expenditure for personal health care. With respect to drug costs, all Americans expended $15,098,000,000 for drugs and drug sundries in the calendar year 1978. Of this figure, $3,331,000,000 or 22% of the nationwide total was spent by persons 65 years of age and older. On a per capita basis, older persons' drug costs are nearly twice as much as those of younger persons.

   Older Americans pay for the overwhelming majority of these costs out of their own pockets. Medicare provides no reimbursement for prescription drugs. Medicaid is available only for the poor, and indeed only provides benefits for approximately 50% of the poor. Consequently, only 15.6% of drug costs to the elderly are covered by the combination of Medicare and Medicaid and other types of public

The overriding interest of AARP and NRTA in the health care field is to foster and promote efficient delivery to the elderly of the best possible services at the least possible cost, thus making them readily available even to persons living within fixed and limited incomes. Amici steadfastly maintain that elimination of all anti-competitive barriers in the drug industry is essential to the achievement of this ultimate goal.

Brand name manufacturers develop an overwhelming head-start in the market for a particular drug, Cyclospasmol being a prime example. By virtue of their patent, they enjoy a seventeen year product monopoly, and direct an exhaustive advertising campaign toward physicians. As a consequence, most physicians identify a drug with its brand name and write prescriptions accordingly.

In recognition of the vast competitive superiority thus obtained by brand-name manufacturers, the legislatures of 49 states have adopted so-called "generic drug substitution" statutes which either require or allow the dispensing pharmacist to substitute a generic drug, unless the physician otherwise directs. These statutes are evidence of the pervasive local interest in fostering effective competition in the pharmaceutical market in order to achieve some measure of cost containment.

Instead of accommodating this social interest, the Second Circuit has ignored it, and indeed done it considerable violence, by effectively granting brand-name producers a monopoly over the color in which their drug is produced.

The color in which drugs are packaged involves far more than aesthetics; it is a vital competitive characteristic. During the period in which their patent is in effect, brand-name

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assistance. Thus the elderly must privately finance a full 84.4% of these drug costs, largely out of their fixed, and increasingly inadequate incomes. Gibson, *National Health Expenditures*, 1979, 2 HEALTH CARE FINANCING REVIEW 1 (Summer 1980); Fisher, *Differences by Age Groups in Health Care Spending*, 1 HEALTH CARE FINANCING REVIEW 4 (Spring 1980).

companies establish a color which identifies a particular drug in the eyes of dispensers, *i.e.* physicians, hospitals, and pharmacists, as well as in those of the patient. The introduction, after expiration of the patent monopoly period, of a generic equivalent dressed in a different color will be met with substantial resistance, by reason of which the generic competitor will be foreclosed from a substantial pocket of the market.

Thus, it is predictable that the Second Circuit's decision, severely restricting the ability of generic manufacturers to dress their drugs in the "accepted" colors used by the brand-name producers, will stifle competition and prices will inevitably rise. This threat to the continued availability of lower-priced, bioequivalent generic drugs, and the downward pressure on prices caused by their competition with brand-name drugs, seriously prejudices older persons, a category of Americans with expanded need for the drugs, but with often limited means to pay for them.

ARGUMENT

Amici respectfully join in the legal arguments advanced by the Petitioners. We respectfully highlight below several points of direct concern to AARP and NRTA.

POINT I

THE SECOND CIRCUIT'S DECISION GRANTS BRAND-NAME DRUG MANUFACTURERS AN UNFAIR MARKETING ADVANTAGE BY VIRTUE OF THE FUNCTIONALITY OF DRUG COLOR AND THUS THREATENS TO DEPRIVE ELDERLY CONSUMERS OF THE BENEFITS PRODUCED BY CONTINUED COMPETITION BY GENERIC DRUG MANUFACTURERS

The colors used in drug packaging are functional in various ways, particularly as regards the elderly. The colors serve to identify the *medicine,* but not its source. As expressly found by the District Court,[1] many patients, especially elderly patients, associate the color of a drug with its therapeutic effect. Since the brand-name product, in the color of the capsule containing it, is the exclusive source of a drug while it is under patent, a drug will be identified as "my little blue heart pill." When a bioequivalent generic drug becomes available, but in a different color, there is considerable distrust with respect to the generic alternative. This distrust may lead to a lack of patient compliance in a state such as New York, which has adopted a mandatory generic drug substitution statute. When faced with patient resistance to drugs packaged in an unfamiliar color, physicians will prescribe the brand-name drug to insure that reluctant patients will take it. Indeed, problems with patient compliance may convince some physicians to insist as a matter of policy that pharmacists fill prescriptions with brand-name

1. See Appendix C to the Petition, p. 63a.

drugs, thereby denying all their patients access to lower-priced generics.

Second, even if patients eventually accept variations in color, they do so only after considerable anxiety and confusion. This can often result in the patient being deprived of the so-called "placebo effect" experienced by many patients, *i.e.* the psychological healing power caused by the confidence and assurance of a patient taking medication that he has been advised would help him.

Third, many elderly patients who take multiple medications identify each drug by its color. Color variations in the same medicine would upset the identification procedures employed by elderly patients, and create widespread confusion.

Fourth, the potential for confusion has led hospitals, pharmacies and wholesalers to refuse to purchase generic drugs colored differently than the brand-name drugs.

Fifth, uniform drug coloring can save lives, as it can serve to identify drug overdoses for physicians and emergency personnel acting in life-threatening situations.

This tendency of drug color to identify the medicine is heightened with respect to a drug such as cyclandelate. Cyclandelate is prescribed for long-term use, and usually to elderly patients. The long-term use enables the drug to become identified by its color, and color identification is more necessary for elderly patients who frequently take several drugs on a daily basis.

In light of the functionality of drug color, the District Court found, as a matter of fact, that "to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage."[2] The District Court further found that "color is an important ingredient in the commercial success of the product."[3]

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2. *Id.* at 63a.

3. *Id.*

Labeling these functionality aspects to the issue, "unconvincing,"[4] the Second Circuit held that the generic manufacturers' imitation of the color in which respondent packaged its Cyclospasmol constituted "contributory trademark infringement" violative of Section 32 of the Lanham Act, 15 U.S.C. § 1114.

The Court of Appeals reasoned that the generic manufacturers should have reasonably anticipated that some druggists might intentionally or accidentally apply respondent's trademark to cyclandelate.[5] Because this possibility will always exist, the Court of Appeals has effectively granted a monopoly over color to brand-name drug manufacturers, and given them an unfair advantage over generic competitors who must sell the generic drug in a far less marketable color.[6] Consequently, the Second Circuit, in a radical departure from settled law,[7] has granted proprietary rights in color in the absence of "secondary meaning" and despite evidence of functionality, and has sharply contradicted the federal policy, as enunciated by this Court, favoring the exact copying of unpatented merchandise.[8] In so doing, it seems to have forsaken the interest of the public in general, and that of the elderly in particular, in favor of the profit interest of the drug manufacturers.

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4. *See* Appendix D to the Petition, p. 85a. As specifically noted by Judge Mulligan in his dissenting opinion (*Id.* at 91a) the majority did not characterize Judge Nickerson's findings with respect to the functionality of drug color as "clearly erroneous."

5. See *Id.* at 82a-83a.

6. The Second Circuit majority was particularly impressed by the results of test shoppings at 83 pharmacists located in the New York metropolitan area. Yet only one of these pharmacists dispensed cyclandelate while labelling it Cyclospasmol, without indicating to the patient in some fashion that he was being given a generic drug. It seems that the Majority has held that whenever palming-off occurs, a manufacturer should have reasonably anticipated it, thus removing any element of scienter from contributory trademark infringement.

7. *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Upjohn Co. v. Schwartz*, 246 F.2d 254 (2d Cir. 1967).

8. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964); *Compro Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 238 (1964).

To the extent that generic manufacturers cannot compete with the brand-name producers in light of the color monopoly granted by the Court of Appeals in this case, and thus are forced out of the market, the brand-name manufacturers will then enjoy restoration of their product monopoly which had expired along with their patent. This would remove any hope for cost containment in the pharmaceutical industry.

To the extent that generic manufacturers manage to remain in the market, drug identification by color will no longer be possible, because of the inevitable claim of trademark infringement. Furthermore, patients or physicians whose confidence depends upon the functionality of drug color must suffer the higher price commanded by the brand-name companies. These functional aspects principally affect the elderly, and thus will be mainly paid for by a group of Americans least able to afford it.

CONCLUSION

Amici have a special interest and concern in expanding the competitive forces at work in the pharmaceutical market. Granting brand-name producers a monopoly over product color, in light of its functional nature, will seriously limit or eliminate these competitive forces, will preclude drug identification through uniform coloring, and will reserve the functional benefits of drug color to those willing and able to pay higher prices for it.

WHEREFORE, the decision of the United States Court of Appeals for the Second Circuit should be reversed.

Respectfully submitted,

MILLER, SINGER, MICHAELSON
& RAIVES, P.C.
555 Madison Avenue
New York, New York 10022
(212) 752-8830
Attorneys for *Amici Curiae*

ALFRED MILLER,
Counsel of Record

RICHARD C. EBELING,
Of Counsel

Dated: November 23, 1981
New York, New York

EXHIBIT "A"

[Letterhead of
Miller, Singer, Michaelson & Raives, P.C.]

November 11, 1981

BY HAND

Milton A. Bass, Esq.
Bass, Ullman & Lustigman
747 Third Avenue
New York, NY 10017

Peter T. Cobrin, Esq.
Kirschstein, Kirschstein, Ottinger
& Cobrin
666 Fifth Avenue
New York, NY 10103

Robert V. Marrow, Esq.
Salon, Marrow & Dyckman
41 East 42nd Street
New York, NY 10017

Re: *Inwood Laboratories v. Ives Laboratories*

Gentlemen:

In conformity with Rule 36(2) of the United States Supreme Court Rules of Practice, we request your written consent to our filing of a brief *amici curiae* in the captioned matter on behalf of the American Association of Retired Persons and the National Retired Teachers Association. Please acknowledge your consent by signing the attached copy of this letter at the

space indicated and returning the same via the messenger who will be standing by.

We appreciate your cooperation.

Yours very truly,

RICHARD C. EBELING

/s/ MILTON A. BASS

/s/ PETER T. COBRIN

/s/ ROBERT V. MARROW

EXHIBIT "B"

[Letterhead of
Miller, Singer, Michaelson & Raives, P.C.]

November 11, 1981

BY HAND

Marie V. Driscoll, Esq.
Cooper, Dunham, Clark, Griffin
& Moran
30 Rockefeller Plaza
New York, NY 10112

Re: *Inwood Laboratories v. Ives Laboratories*

Dear Ms. Driscoll:

This will confirm our telephone conversation of yesterday, November 10, during which you gave consent, on behalf of Ives Laboratories, to our filing of a brief *amici curiae* on behalf of the American Association of Retired Persons ("AARP") and the National Retired Teachers Association ("NRTA"). I represented to you that the brief would be served by hand, instead of by mail.

Since our conversation, I have re-reviewed the Rules of Practice of the United States Supreme Court, and in particular Rule 36(2) thereof, and have discovered that Respondent's consent must be expressed in writing. Therefore, please acknowledge your consent to our filing of an *amici* brief by

signing the attached copy at the indicated place and returning the same to us via the messenger who will be standing by.

We deeply appreciate your cooperation and courtesy.

Yours very truly,

RCE/ct

RICHARD C. EBELING

Respondent consents to the filing of a brief *amici curiae* by AARP and NRTA in the captioned matter:

/s/ MARIE V. DRISCOLL

Marie V. Driscoll
Attorney of Record
for Respondent
Ives Laboratories, Inc.

FILED
NOV 30 1981
CLERK

Nos. 80-2182; 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

BRIEF FOR THE GENERIC PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

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Of Counsel:

AMSTER, ROTHSTEIN & ENGELBERG

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Nos. 80-2182; 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERBY PHARMACEUTICAL CO., INC.,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

BRIEF FOR THE GENERIC PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

I. Authority to File

This Amicus Brief is presented to the Court under Rule 36.2 and letters of consent from Petitioners and Respondent are on file with the Clerk of the Court.

II. Interest of Amicus Curiae

The Generic Pharmaceutical Industry Association was formed in 1980 by a group of independent generic drug manufacturers, distributors and retailers to seek solutions to common problems having an economic impact on the distribution and sale of generic drugs. Many of these problems relate to the implementation of recently enacted laws in 49 states, the District of Columbia and Puerto Rico which are intended to encourage the substitution of lower cost, therapeutically equivalent generic drugs for unpatented higher priced, heavily promoted brand name drugs as a means of reducing health care costs. The

Association's member companies account for a substantial portion of the sales of independently manufactured generic prescription drugs.

The questions raised in this case transcend the specific petitioners and facts and have a direct economic impact on the generic pharmaceutical industry, government medical reimbursement programs and consumers of prescription drugs. Prior to the decision in the case under review and similar recent decisions in the Third Circuit, it was generally believed that the size, color and shape of prescription drugs were functional and could not be exclusively appropriated by a single manufacturer. Dozens of identically colored drugs made by different manufacturers have, in fact, coexisted in the marketplace for many years withot engendering any legal controversy. The recent decisions not only create uncertainty with regard to the status of those drugs but would eliminate the long accepted and common practice of making equivalent medications in the same colors in the future as patents covering other drugs expire. The members of Amicus are the actual and potential manufacturers of these drugs and will be economically affected by the Court's decision. Consumers will also be affected since the affirmance of the Second Circuit's decision would establish a substantial economic barrier to market entry of new generic drug products after the 17 year patent monopoly expires thereby adversely affecting the function and purpose of the State generic drug substitution laws.

III. Summary of Argument

The Second Circuit decision grants to the manufacturer of a patented drug a strict and perpetual monopoly after expiration of the patent in both the appearance of the drug and the name by which it has come to be commonly known by physicians and consumers. The immediate effect of that decision is to create by judicial action a national policy promoting high drug prices which threaten to force the poor and aged to choose between the allevia-

tion of physical pain and the enjoyment of basic necessities. See *Virginia State Board of Pharmacy* v. *Virginia Citizens' Consumer Council*, 425 U.S. 748, 754, 764 (1976). This novel judicially imposed policy decision directly conflicts with the legislatively established policy of essentially every State to mandate or strongly encourage the substitution of lower cost, therapeutically equivalent generic drugs in situations where the physician's prescription generically identifies the medication by referring to its brand name.

The State substitution laws were enacted after careful analysis of the manner in which prescription pharmaceuticals are dispensed and reflect a belief by the States that the *de facto* conversion of the brand name to a generic designation during the period of patent exclusivity directly contributes to inordinately high drug prices after expiration of the patent monopoly. The substitution laws reprenent State action in aid of the welfare of its citizens which should be given full respect by this Court, absent any conflicting and overriding Federal law or policy which mandates a contrary result. No such law or policy exists.

This Court has long recognized the inherent tension which exists between the monopoly created by the patent system and our system of free enterprise which encourages the unfettered copying of formerly patented products and has struck down every attempt to extend the length of the patent monopoly. *Kellogg* v. *National Biscuit Co.*, 305 U.S. 111, 120-122 (1938); *Singer Mfg. Co.* v. *June Mfg. Co.*, 163 U.S. 169, 185 (1896); *Sears, Roebuck & Co.* v. *Stiffel Company*, 376 U.S. 225, 230 (1964); *Compco* v. *Day-Brite Lighting, Inc.*, 376 U.S. 239 (1964). It has not permitted patent holders to perpetuate their monopolies by claiming exclusive rights in either the name or appearance by which the product was known to the public during the period of patent monopoly. The legitimate interest of the public in knowing the source of origin of the products which became available from multiple sources upon patent expiration has been recognized by this Court and protected by appropriate labeling requirements to prevent unfair competition.

The State substitution laws fully accomodate State and Federal principles of unfair competition by requiring pharmacists to label prescriptions as to source of origin when a generic substitute is dispensed. In New York a failure to adhere to labeling requirements may result in fines, imprisonment, and loss of license. Those seeking to bypass the law are being prosecuted.

The Second Circuit opinion fails to consider the inherent conflict between its decision and both the Federal policy prohibiting the extension of patent monopolies, and the State policy fostering substitution of generic drugs. It avoids that issue by limiting its holding to contributory infringement of the "Cyclospasmol" trademark under Section 32 of the Lanham Act 15 U.S.C. § 1114, and narrowly view this case as a matter arising under Federal trademark infringement law. It ignores the factual findings of the Trial Court, that there was no direct trademark infringement because the term "Cyclospasmol" had become the generic name of the medication at the consumer level and disregards the established line of authority going back to this Court's decision in *Saxlehner* v. *Wagner*, 216 U.S. 375, 380 (1910), which holds that there is no trademark infringement when a manufacturer refers to the trademark of a copied product for the purpose of telling the public what is being copied.

The Second Circuit's attempt to narrow the issue also side steps the Trial Court's factual finding that Respondent Ives failed to prove the color of "Cyclospasmol" had a secondary meaning, i.e., that it indicated a single, albeit anonymous, source of origin. The Circuit Court was duty bound to accept the Trial Court's finding of a failure of proof since it was not clearly erroneous. Accordingly, if the Second Circuit had considered all of the issues raised by the appeal, it would have been left in the anomolous position of enjoining the capsule color under Section 32, while simultaneously finding that the color did not indicate origin.

The Second Circuit opinion also disregarded the unique marketing environment of prescription pharmaceuticals

and failed to differentiate this case from every day shopping situations in which the consumer's purchasing decision may be unfairly influenced by too close a similarity in appearance of adjacently displayed products. Here, as a Federal Trade Commission study has aptly noted, the physician prescribes, the pharmacist dispenses, and the patient pays.[1] No advertising or promotional activities are directed at patients, and prescription drugs are not purchased by choice or on impulse. The average patient neither knows nor cares if the name or appearance of a medication is associated with a single producer. The patients care only that they receive the medication which their doctor prescribed and that it works for the purpose intended. The State substitution laws are, in essence, nothing more than a recognition of this fact.

This case represents an attempt to maintain a monopoly position by erecting new barriers to replace the brand name barrier, which has been somewhat lowered by the State substitution laws, and the price advertising barrier struck down by this Court in *Virginia State Board* v. *Virginia Citizens Consumer Council, supra.* A decision by this Court holding that there can be no monopaly over drug colors does not require this Court to create any exception to establish principles of law. To the contrary, it requires only the application of the principle of *stare decisis.*

IV. Argument

A. The Factors Leading To The Adoption of State Substitution Laws Support The Trial Court's Decision

The Trial Court's decision[2] denying Respondent Ives all relief was based on a number of clearly factual findings having a direct impact on whether the "Cyclospas-

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[1] Staff report to the Federal Trade Commission, Drug Product Selection 96 (1979).

[2] *Ives Laboratores, Inc.* v. *Darby Drug, Inc.*, 488 F.Supp. 394 (E.D.N.Y. 1980).

mol" trademark was directly or contributorily infringed. The Court found that:

1. Respondent Ives was the sole source of the drug from 1962 until the patent covering the product expired in 1972. (455 F.Supp. at 939)

2. Because the drug may be dispensed only on prescription, Ives had not promoted its product to the general public but had spent in excess of Ten Million Dollars ($10,000,000) on advertising and promotion primarily to doctors. This promotion included the personal distribution of free samples and other materials by "detail men" who made numerous personal visits to physicians. (455 F. Supp. at 939; 488 F.Supp. at 396)

3. The proven incidents of mislabeling under the New York substitution law all arose in situations where the physician had prescribed the medication by using its brand name "Cyclospasmol" rather than a generic identifictaion. In the vast majority of cases, substitution occurred in accordance with the New York substitution law. Of the ten instances of such mislabeling actually established at trial, five involved the use of the word "generic" on the label as a modifier for "Cyclospasmol" and nine out of ten pharmacists informed the patient that a generic product had been dispensed. Such mislabeling as occurred stemmed from confusion as to the labeling requirements of the New York generic drug substitution law. (488 F.Supp. at 397, 398)

4. Surveys conducted by Ives demonstrated that a substantial number of patients who were taking "Cyclospasmol" were unable to associate that name or any other name with their medication, and there was no evidence that any of the survey respondents had ever heard of the drug by any name other than "Cyclospasmol" or that they supposed that "Cyclospasmol" was a brand name indicating the source of the drug. (488 F.Supp. at 400)

5. There is no reason to suppose that the word "Cyclospasmol" signifies a source of origin to patients since they have not been the target of sales compaigns and play no role in choosing what drug to buy. Nothing in the record suggests that to them the name signifies anything more than a kind of drug to which they have become habituated. (488 F.Supp. at 400)

6. If patients do not know that the word "Cyclospasmol" designates a single source, it logically follows that a color they associate with that name does not signify a single source to them. In any event, the color of the capsule has significant functional characteristics since it is relied on by patients, physicians and hospitals to identify the medication rather than its source, and any change in the color of a medication would cause confusion and anxiety. (488 F.Supp. at 398-400)

The foregoing factual findings are completely consistent with the rationale underlying the adoption of State substitution laws. Those substitution laws and the factors which led to their adoption are directly relevant here, since they are an essential part of the market environment in which the allegedly infringing acts occurred.

Subsequent to World War II, there was a large increase in the number of available prescription drug products and, accordingly, an increase in the reported instances of duplication and counterfeiting of such products. Some of these drugs were not as safe or effective as the brand name drugs they were imitating. Seizing on this problem, the major pharmaceutical manufacturers spearheaded a national effort which resulted in the passage of State "anti-substitution" laws. These laws prohibited the pharmacist from dispensing any product other than the product specifically identified on the prescription.[3] The

[3] FTC Staff Report, *supra*, note 1 at 146 et seq. The FTC Staff Report contains a thoroughly documented analysis of the role of the manufacturer, physician, pharmacist, patient and State and Federal regulation in the distribution and selection of prescription drugs and the impact of these factors on competition.

anti-substitution laws provided significant economic impetus to increasing emphasis by major pharmaceutical companies on promotional techniques designed to encourage brand name prescribing by physicians.

In 1962, Congress amended the Food, Drug and Cosmetic Act to include provisions requiring manufacturers of new drugs to establish, prior to marketing, that those drugs were safe and effective. See 21 U.S.C. § 321 et seq. The 1962 Amendments also provided for the reevaluation of the efficacy of products which had been approved for marketing between 1938 and 1962. 21 U.S.C. § 355. The FDA also established a code of good manufacturing practices to insure that all products were not only identical in their composition and therapeutic value, but were also safely manufactured.

By the late 1960's, it had become apparent that the amendments to the Food and Drug law were working in a manner which assured that approved generic drugs were equivalent to their brand name counterparts, and this fact began to be publicly expressed by the regulatory experts. For example, the Final Report of the Task Force on Prescription Drugs, U.S. Department of Health, Education and Welfare, February 7, 1969 reported:

> "On the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to public health."

In the ensuing years, similar statements, including the following, were made by FDA officials:

> "On the basis of data we have accrued to date, we cannot conclude that there is a sigificant difference in quality between the generic and brand-name products tested."[4]

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[4] Dr. Henry F. Simmons, Director of FDA's Bureau of Drugs, *FDA Consumer Magazine*, March, 1973.

> "All drugs, whether they are sold under their brand names or their generic names, must meet the same FDA standards for safety, strength, purity and effectiveness. All drug manufacturers, big or small, are subject to FDA inspection and must follow the Agency's Current Good Manufacturing Practice Regulations. That is why FDA believes there is no significant difference in quality between generic and brand name drugs."[5]

The established equivalence of generic drugs should logically have led to an immediate and rapid expansion in the rate of sale of those products in view of their significantly lower cost to consumers. Numerous reported studies over the past ten years have documented the significantly lower cost of generic drugs and the savings which are realized on generic drug purchases.[6] This Court has taken notice of studies establishing price differentials of up to 1200% for the same amounts of a specific drug and concluded that "the phenomenon of widely varying drug prices is apparently national in scope."[7]

Despite the enormous price differentials, generic pharmaceutical products account for only a minute share of the prescription pharmaceutical market. There can be no doubt in this case that the use of the brand name (Cyclospasmol) as if it were the generic name (Cyclandalate) during the patent monoply period is directly responsible for that result. During the ten-year period from 1968 to 1977, only 10 to 14% of all new prescriptions were writen by physicians using the generic name of the medication, and that figure is inflated by a higher percentage of

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[5] Annabel Hecht, FDA Office of Public Affairs, *FDA Consumer Magazine*, February, 1978.

[6] FTC Staff Report, *supra*, footnote 1, at 196-219; Consumer Reports, January, 1975, at p. 48.

[7] *Virginia State Board of Pharmacy* v. *Virginia Citizens' Consumer Council, Inc.*, *supra*, at 754.

generic prescriptions for certain antibiotics.[8] Prescriptions using the brand name rather than the generic name of the medication account for over 90% of the prescriptions of most drugs and, particularly, those drugs which were available from only a single source during the period when they were covered by unexpired patents. One recent study reports that twelve formerly patented drugs each retained more than a 90% share of the drugstore market and more than an 80% share of the hospital market, after the patents expired. Six of the drugs retained more than a 97% share of both markets.[9]

None of the foregoing statistics are particularly surprising in view of the vast promotional efforts of pharmaceutical firms which, as noted by the Trial Court in this case, ignore the consumer and are primarily directed at the prescribing physician. The drug industry spends an average of $4,000 to $5,000 annually per private practitioner.[10] The result of this exclusive brand name promotion during the period of the patent monopoly is to leave the patent holder with a continuing monopoly after the patent expires which is strong enough to limit effective price competition for prescription drugs. Indeed, the combination of lack of advertising at the consumer level and brand-name prescribing at the physician level, makes it highly unlikely that any consumer is ever actually exposed to the generic name of the product during the patent monopoly period, when the product is only available from a single source. It is not surprising, therefore, that widely prescribed medications such as Darvon, Valium and Librium, to name only a few ostensible trademarks,

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[8] Annual Prescription Survey by the Albany College of Pharmacy, *Medical Marketing and Media*, April, 1978, at 24; Multi-Source Drugs: An Acceleration in the Use of Lower-Costing Substitutes? *Reynolds Securities Information Report*, May 13, 1977.

[9] Patent Term Extension in the Pharmaceutical Industry, Office of Technology Assessment, July, 1981, at 33.

[10] Donald Kennedy, Commissioner of Food and Drugs, *The New England Journal of Medicine*, April 13, 1978, at 846; *Consumer Reports*, January, 1975, at 52.

are actually household generic words and that consumers do not know or associate the names propoxyphene hydrochloride, diazepam or chlordiazepoxide HCL with these products, although they are, in fact, the true generic names.

It is against this backdrop, that the States, acting to protect the health and welfare of its citizens, have modified the anti-substitution laws and enacted laws which encourage the substitution of lower-cost therapeutically equivalent generic drugs for the brand name product actually set forth on a prescription.[11] This State policy is strongly reinforced by Federal policy. The Maximum Allowable Cost (MAC) Program instituted by the Department of Health, Education and Welfare limits third party reimbursement for prescription drugs under the Medicaid program to the lowest price at which a particular multi-source drug is generally available.[12] Other Federal agencies including the Veterans Administration, Department of Defense and Public Health Service have been buying lower-costing generic substitutes on a competitive bid basis for decades, even during the period when the originator's product was still covered by unexpired patents. *Carter-Wallace* v. *United States*, 496 F2d 535 (Ct. Cl. 1974).

Although the mechanics of the State substitution laws vary from State to State, they are all based on a common principle, namely, that the appearance of a brand name on a prescription does not automatically mean that the brand name product will be dispensed. Depending upon the requirements of a particular State, the physician must give some further indication that the use of the brand name was actually intended to command the pharmacist to dispense the brand name product and was not merely being used as a means of describing a type of medication, i.e., a generic use. The New York substitution law,[13] for ex-

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[11] *Pharmaceutical Society of N.Y. Inc.* v. *Lefkowitz*, 454 F. Supp. 1175 (S.D.N.Y. 1978), *aff'd* 586 F2d 953 (2d Cir. 1958).

[12] FTC Staff Report, *supra*, footnote 1, at 134.

[13] N.Y. Educ. Law § 6810, 6815, 6816, 6816(a) (McKinney's Supp. 1981).

ample requires the prescription form to recite that it will be filled generically unless the doctor signs over the line stating "dispense as written". The other signature line which must appear on the form reads "substitution permissible, and a signature on that line permits the pharmacist to substitute a less expensive generic equivalent. Other State laws make substitution of a generic equivalent mandatory, unless the physician vetoes such substitution by writing the words "dispense as written", "do not substitute", or similar terminology on the prescription form.[14] Most of the State substitution laws also include provisions for determining what drugs may or may not be substituted; labeling requirements; and appropriate enforcement remedies to insure compliance with their provisions.

The State substitution laws are aimed squarely at the problem caused by brand name prescribing and have no application whatsoever to a generically written prescription since such a prescription clearly leaves specific drug product selection to the discretion of the pharmacist. It was because the States recognized that the average physician does not use and may not know the generic names, that the substitution laws were enacted.

The States were obviously mindful of the fact that the brand names are Federally registered trademarks and a broader use of them could not be authorized without creating a conflict with Federal trademark law. The substitution laws accordingly represent a State law codification of this Court's decision in *Saxlehner* v. *Wagner*, 216 U.S. 375 (1910), and the cases which have adopted its compelling logic. See *Societe Comptoir de L' Indus., Etc.* v. *Alexander's Dept. Stores*, 299 F2d 33 (2d Cir. 1962); *Smith* v. *Chanel, Inc.*, 402 F2d 562 (9th Cir. 1968). Those cases make it clear that a manufacturer who exercises the free enterprise right to copy an unpatented product also has a right to refer to the competitor's trade-

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[14] See Warner, Consumer Protection and Prescription Drugs: The Generic Substitution Laws, 67 Ky. L. J. 389 (1979) for an excellent discussion of the specific provisions of State substitution laws and the differences between individual States.

mark in order to truthfully inform the public that his product is a copy. If this were not the case there would be no way of informing potential buyers that a product was, in fact, a copy. The State substitution laws do no more than permit a physician to refer to a trademark as a means to convey instructions to the pharmacist that a product equivalent to the product bearing the brand name be dispensed.

B. Cyclospasmol Has Become A Generic Term and Its Use At The Consumer Level Does Not Constitute Trademark Infringement

Although the State substitution laws represent an attempt to nibble at the edges of Respondent Ives' continuing monopoly after the patent expires, they can never be wholly effective for their intended purpose given the entrenchment of the brand name in the physicians' mind and the limitations on State action imposed by Federal trademark laws. But this Court has already defined a more direct method for preventing the perpetuation of brand name monopoly power created during the term of a patent. In both *Singer Mfg. Co.* v. *June Mfg. Co.*, 163 U.S. 169 (1885) and *Kellogg Company* v. *National Biscuit Company*, 305 U.S. 111 (1938), this Court held that upon the expiration of a patent, the name by which the patented article came to be known during the patent monopoly period passed to the public along with the right to make the article.[15] As the Court stated in *Singer:*

> "To say otherwise would be to hold that, although the public had acquired the device covered by the patent, yet the owner of the patent or the manufacturer of the patented thing had retained the designated name which was essentially necessary to vest the public with the full enjoyment of that which had be-

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[15] This Court has consistently resisted all attempts to extend the patent monopoly beyond its expiration date by any technique. *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249 (1945); *Brulotte* v. *Thys Co.*, 379 U.S. 29 (1964); *Sears, Roebuck & Co.* v. *Stiffel Company, supra.*

come theirs by the disappearance of the monopoly." Id. 163 U.S. at 186.

In *Singer* this rationale was applied to the name "Singer" even though it was the surname of the manufacturer, because the patented sewing machines had come to be identified by that generic name and not by the generic name "sewing machines" during the patent monopoly period.

Respondent Ives may argue that the rationale of *Kellogg* and *Singer* cannot apply here because "Cyclospasmol" has an "official" generic name (Cyclandalate) which is designated by the "USAN and the USP Dictionary of Drug Names" and is therefore not the name by which the patented product came to be known during the patent period. Such an argument cannot obscure the fact that the general public neither knows nor cares about the official name of the product set forth in a technical dictionary to which it has no occasion to refer. The plain fact is that the only name which was ever exposed to consumer view was "Cyclospasmol" and this was due to the deliberate promotional activity of Respondent Ives at the physician level, while simulataneously refraining from promotion at the consumer level. Ives has maintained a substantial monopoly over prices and competition since the "Cyclospasmol" patent expired due to its continuing monopoly over the only name by which the drug was known. The relinquishment of the name "Cyclospasmol" is essentially necessary to vest the public with the full enjoyment of the expired patent monopoly.

There is an independent line of precedent which leads to the conclusion that "Cyclospasmol" has become a generic designation at the consumer level. *Bayer Co., Inc.* v. *United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921). See also *DuPont Cellophane Co.* v. *Wax Products Co.*, 85 F2d 75 (2d Cir. 1936). In *Bayer*, based upon marketing practices virtually indistinguishable from those found by the Trial Court with respect to "Cyclospasmol", Judge Learned Hand held that "Aspirin" had become a generic name since

it failed to convey to consumers that products bearing that name identified a single, albeit anonymous, source of origin. The Trial Court quite properly paraphrased Judge Hand in finding: (488 F.Supp. at 400)

> "No doubt to physicians and pharmacists the word "Cyclospasmol" signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaigns, and they play no role in choosing what drugs to buy. Nothing in the records suggest that they 'understand by the word anything more than a kind of drug to which for one reason or another they [have] become habituated.' [citing *Bayer* at 510]. Such patients as read their prescriptions do not attribute to "Cyclospasmol" 'any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue.' Id."

That Cyclospasmol has become generic at the consumer level[16] is further supported here by several facts which were not present in *Bayer*. First, in half of the mislabeling instances from Respondent Ives' shopping survey, under the New York substitution law, the pharmacist used the word "generic" or an abreviation thereof in conjunction with "Cyclospasmol", and in nine out of the ten instances the patient was informed that a generic substitute was being dispensed. These facts demonstrate that the word "Cyclospasmol" was being used generically, and there was no trademark infringement even if there was a failure to fully comply with the labeling requirements of the State substitution law. Second, during the years in which Ives was the sole source of "Cyclospasmol", the anti-substitution laws were in effect and brand name prescribing was dominant, thereby assuring that consumers would not be exposed to any other name for the product.

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[16] This conclusion, which is supported by the Trial Court's findings, would not invalidate the Federal trademark registration owned by Ives but would limit its enforceability to infringement at the physician and pharmacist level as in *Bayer*.

Third, the nature of the word "Cyclospasmol" is such that it is highly suggestive, if not merely descriptive of the medication. Indeed, in the arguments submitted by Ives to obtain its Federal trademark registration, Ives acknowledged that the "Spasmol" suffix was descriptive of the spasmolytic properties of the medication and "carries in itself no significance as to the origin of the goods." Ives also argued that the products to which the name would be applied "by their very nature and purpose are likely to be known only to the drug trade and the medical profession and to be purchased and used only on the prescription of a physician and under his direction.'"[17]

The State substitution laws demonstrate a belief on the part of the 51 legislatures which studied the problem and enacted such laws that the brand names of prescription pharmaceuticals are the common designation by which drugs are known. Federal legislation has also recognized the fact that brand names tend to function as the generic name of the product. The 1962 Amendments to the Food, Drug and Cosmetic Act included a requirement that advertisements or other printed matter issued by drug manufacturers include the generic name of the product in type at least half as large as the brand name. 21 U.S.S. § 352. But such printed material never reaches the consumer, and the physician is obviously converted to essentially exclusive use of the brand name by heavy promotion. The plain fact is that the studies conducted more than fifteen years after enactment of these statutes establish that over 90% of prescriptions are written by brand name, even after the patents covering those prescription drugs have expired.

The owner of a patent covering a prescription drug has an ample opportunity during the period of patent exclusivity to develop both a generic product identification and a trade mark identification and to encourage the use of both by physicians and pharmacists. If that is done, the good will associated with the medication will pass into the

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[17] United States Patent and Trademark Office, File History of U.S. Registration No. 602,919.

public domain when the patent expires and the good will associated with the trademark and the established experience and reputation of the original manufacturer will provide a fair competitive advantage without interfering with competition. The facts in this case unequivocally establish that this has not occurred and that the continuing monopoly over the name by which the medication has become known creates an unwarranted perpetual monopoly.

C. There Has Been No Contributory Infringement of the "Cyclospasmol" Trademark

In the absence of direct infringement, there can be no contributory infringement, and the Trial Court's finding that "Cyclospasmol" is a generic term at the consumer level eliminates the charge of trademark infringement under Section 32 of the Lanham Act. However, even if direct infringement exists, the evidence does not logically or legally support the conclusion that the acts of Petitioners contributed to that infringement.

The Second Circuit held that the criteria for the application of the doctrine of contributory infringement are set forth in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D.Mass. 1946) *aff'd* 162 F2d 280 (1st Cir.) *cert. denied* 322 U.S. 809 (1947). In so holding, the Second Circuit failed to consider whether there was any causal connection between the acts of Petitioners in selling their products to the pharmacist and the acts of the pharmacists in dispensing and labeling those products.

Snow Crest did not involve State laws permitting or encouraging prescription drug substitution. Accordingly, in that case any express or implied suggestion to the retailer that one product be substituted for another could only have been made in aid of an act of unfair competition. Under those circumstances, there was every reason to hold the manufacturer jointly liable with the retailer for the "passing off" which occurred as a result of their joint action. Here, the State substitution laws makes it perfectly permissible for the manufacturer's product to be legally substituted for the brand name product. Ac-

cordingly, a suggestion by a generic drug manufacturer that its product can be substituted for the brand name product does no more than promote the aims of State law designed to lower the patient's drug costs. The comparative advertising engaged in by Petitioners did precisely that in a manner which has long been approved. *Saxlehner* v. *Wagner, supra.* Moreover, the evidence in this record establishes that Petitioners' identically colored product was used for lawful substitution in the overwhelming majority of cases where it was dispensed. These facts undermine the finding that any causal link exists between the color of the products and any wrongful use of the word "Cyclospasmol" by the pharmacist.

Given the substantial legal use to which Petitioners' generic drug product could and was put as a matter of State law and policy, it was incumbent on Respondent Ives to prove not merely that Petitioners had suggested substitution, but that they had expressly or impliedly promoted *illegal* substitution. This distinction, which exists in other areas of intellectual property law was not recognized by the Second Circuit. For example, contributory infringement of a patent will not be found to exist unless the product sold is especially adapted for use in an infringing situation and has no substantial non-infringing use, unless, of course, the infringement is actively induced by the manufacturer. 35 U.S.C. § 271(b), (c); *Dawson Chemical Co.* v. *Rohm Haas Co.*, 448 U.S. 176 (1980). The drugs sold by Petitioners have a very substantial State protected non-infringing use namely, as lawful substitutes. Furthermore, the Trial Court here made a factual finding that there is no evidence to support the proposition that Petitioners, directly or by implication, suggested that pharmacists engage in acts of mislabeling or substitution which are illegal under New York State law and which could result in fines, imprisonment, and loss of license.

A causal link must also be established between the alleged acts of infringement and the relief awarded to prevent their continuance. In that regard, the decision of this Court in *Warner & Co.* v. *Lilly & Co.*, 265 U.S. 526

(1924) is far more relevant than the *Snow Crest* rationale on which the Second Circuit relied. The basic facts in *Warner* are essentially identical to those involved here, in that an identically colored pharmaceutical product was involved. There, although this Court found that substitution was improperly suggested by the distributor, it limited relief to labeling of the product with affirmative warnings against substitution, and did not enjoin the continued sale of the identically appearing product. It is of more than passing interest that no State substitution laws existed at the time *Warner* was decided by this Court.

D. The Establishment of a Monopoly Over The Color of a Drug Cannot Be Justified As A Matter of Law

Until the recent group of decisions barring the generic drug manufacturer from selling identically colored pharmaceutical capsules[18], the cases dealing with drug products uniformly rejected the attempts to enjoin the use of the same color, even in instances where there was evidence to establish acts amounting to wrongful substitution or passing off at the consumer level. *Warner & Co.* v. *Lilly & Co., supra; Norwich Pharmacal* v. *Sterling Drug, Inc.*, 271 F2d 569 (2d Cir. 1959), *cert. denied* 362 U.S. 919 (1960); *Upjohn Co.* v. *Schwartz*, 246 F2d 254 (2d Cir. 1957); *Smith, Klein & French Laboratories* v. *Clark & Clark*,, 157 F2d 725 (3rd Cir. 1946); *Marion Laboratories, Inc.* v. *Michigan Phar-*

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[18] *SK&F Co. Premo Pharmaceutical Lab*, 625 F2d 1055 (3rd Cir. 1980); *Merrill-National Labs, Inc.* v. *Zenith Labs, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977); *Pennwalt Corp.* v. *Zenith Labs, Inc.*, 472 F.Supp. 413 (E.D. Mich. 1979); *A. H. Robins Co.* v. *Medicine Chest Corp.*, 206 U.S.P.Q. 1015 (E.D. Mo. 1980); *Hoffman La Roche* v. *Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980); *Boehringer-Ingelheim GmbH* v. *Premo Pharmaceutical Laboratories*, Civil Action No. 79-358, District of New Jersey, Memorandum Opinion, September 24, 1980; *Biocraft Laboratories, Inc.* v. *Merck & Co., Inc.*, Civil Action No. 77-693 District of New Jersey, Memorandum Opinion, October 2, 1980.

macal Corp., 338 F.Supp. 762 (E.D. Mich. 1972).[19] In each of the foregoing cases where relief was granted, relief was limited to some form of labeling or notice which would serve to prevent the drug in question from being passed off as the product of the original manufacturer.

The reasons why relief was totally barred or severely limited in the foregoing cases are succinctly set forth in this Court's decisions in *Sears* and *Compco*. Those decisions, however, did not establish any new unfair competition law, but merely held that the fundamental concepts with respect to the interface between unfair competition and free competition expresed in earlier cases preempted any contrary State laws. It was already long established by this Court's decisions in *Singer Mfg. Co.* v. *June Mfg. Co., supra; Kellogg Company* v. *National Biscuit Company, supra;* and *Saxlehner* v. *Wagner, supra,* that a product which is in the public domain can be freely copied by anyone and that the right to copy not only includes the right to call a product by its generic designation, but even to refer to the originator's trademark as a means of informing the public as to what is being copied. Unfair competition occurs only when a competitor attempts to sell a product in a manner which confuses the public as to the source of origin of the product. The most deliberate form of such confusion is the "passing off" of the product of one manufacturer as that of another without informing the purchaser. But even in such a case, the relief will be limited to prevention of the passing off and not the copying. As this Court stated in *Kellogg:*

> "Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights in a form in which the public has become accustomed to see the article and which, in the minds

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[19] The only pharmaceutical product cases found in which the appearance of the product was actually enjoined are the Dexadrine cases, *Ross-Whitney Corp., et al.* v. *Smith Klein & French Laboratories*, 207 F2d 190 (9th Cir. 1953); *Smith, Klein & French Laboratories* v. *Brouder*, 125 U.S.P.Q. 299 (S.D. Tex. 1959). However, both of those cases involved a unique pill shape in addition to the color.

> of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind. Kellogg Company was free to use the pillow shaped form, subject only to the obligation to identify its product lest it be mistaken for that of the plaintiff." 305 U.S., at 120.

Similarly, in applying the foregoing principles, this Court in *Compco* concluded that a feature of a product (decorative ribbing on a light fixture) could be freely copied by anyone, even though that feature had acquired a "secondary meaning", and State law could do no more than provide for appropriate labeling as to source of origin in order to prevent passing off.[20]

The authorities also uniformly hold that the definition of what may be considered "functional" is extremely broad and extends not only to those features of a product having a useful purpose but also to any feature which is important to the commercial success of the product. *West Point Manufacturing Co.* v. *Detroit Stamping Co.*, 222 F2d 581 (6th Cir. 1955); *Pagliero* v. *Wallace China Co.*, 198 F2d 339 (9th Cir. 1952). See also *American Safety Table Company* v. *Schreiber*, 269 F2d 255 (2d Cir. 1959). Moreover, irrespective of such distinctions as can be drawn between so-called "functional" and "non-functional" features, the party seeking to enjoin the use of either has the burden of proving that the feature has

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[20] The argument that *Sears* is a State law preemption case and does not apply to § 43 of the Lanham Act (15 U.S.C. 1125(a)) leads nowhere. There is nothing in either the language or legislative history of § 43(a) which would indicate a congressional intent to deviate from the principles expressed in *Kellogg*. See *L'Aiglon Apparel* v. *Lana Lobell, Inc.*, 214 F2d 649 (3rd Cir. 1954); *Colligan* v. *Activities Club of New York Ltd.*, 442 F2d 686 (2d Cir. 1981). Indeed, until this case, the Second Circuit has refused to extend § 43(a) to product features relying on this Court's opinion in *Sears* as establishing that proper labeling is sufficient relief. *Bose Corporation* v. *Linear Design Labs, Inc.*, 467 F2d 304, 309 (2d Cir. 1972); *American Rolex Watch Corp.* v. *Ricoh Time Corp.*, 491 F2d 877 (2d Cir. 1974).

acquired secondary meaning, i.e., that it has origin-indicating significance. *Norwich Pharmacal Company* v. *Sterling Drug, Inc., supra,* at 571; *Frederick Warne & Co., Inc.* v. *Book Sales, Inc.,* 481 F.Supp. 1191, 1195 (S.D.N.Y. 1979); *International Election Systems Corporation* v. *Shoup,* 452 F.Supp. 684, 710 (E.D. Pa. 1978).

Obviously, in all but the most exceptional circumstances, injunctive relief will not be granted which encroaches upon the right to copy products in the public domain. It will not be granted at all if the feature has functional attributes, in the broad sense of the term, irrespective of secondary meaning, and also will not be granted if secondary meaning is not proved, irrespective of functionality. It is for this reason that the prior decisions of this Court and others involving the color of drug products have uniformly refused to enjoin copying and have limited the relief granted to some form of labeling or identification.

The Second Circuit's opinion does not even deal with the topic of secondary meaning and disregards the Trial Court's specific finding that Respondent Ives failed to prove secondary meaning. That finding was supported by substantial evidence and was not clearly erroneous. Indeed, the Trial Court specifically found that Ives' survey was flawed and failed to even show that patients associated the name "Cyclospasmol" with a single source, let alone the color of the product. Moreover, to the extent that the Second Circuit's opinion can be interpreted as implicitly dealing with the question of secondary meaning, it erroneously shifted the burden of proof on that issue to Petitioners. Thus, its analysis of the color issue begins with the following statement:

> "Appellees have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically colored, look alike cyclandalate capsules instead of capsules of a different color, size or

shape which would minimize the practice of mislabeling, illegal substitution or confusion.'"[21]

But Petitioners have offered the most persuasive reason. They wish to copy a product on which the patent has expired. The burden is on Ives to establish a substantial reason why petitioners should not be permitted to engage in this act of free competition.

The Second Circuit opinion also erroneously reverses the standard to be applied in assessing the functionality of the drug color. The Triaal Court found, based on expert testimony, that elderly patients associate the appearance of their medication with its therapeutic effect and would suffer confusion and anxiety if the color of their medication were changed;[22] that patients comingle drugs in a single container and then rely on the appearance of the drugs to determine which medication to take; that color has some utility to doctors in hospital emergency rooms as a means of drug identification; and that color is a factor in the purchase decisions of hospitals, pharmacies and wholesalers in the light of the potential for confusion of medications. Many of these findings are reinforced by the actions of Respondent Ives and others who claim rights in drug colors. If coolor was truly intended to designate origin rather than product, it would obviously make more sense for each company to use the same color for all of its products rather than a different color for

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[21] The decisions in New Jersey cited in footnote 18, *supra*, take an even more direct and equally erroneous approach and hold that proof of copying raises a strong, if not irrebuttal, presumption of secondary meaning thereby shifting the burden of proof to the copyist. This concept which is derived from cases involving packaging simulation is totally inapplicable to a product configuration case in view of *Kellogg*, *Sears* and the other authorities discussed herein.

[22] In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, *supra*, at 763 ,this Court took note of the significantly higher rate of chronic illness among the aged and the resulting higher level of drug expenditures by this group.

each product and even each dosage of the same medication. Nor would there be any reason to include a Product Identification Section in the industry sponsored Physicians Desk Reference which includes color photographs to help doctors identify each drug. These telltale signs of the utility and functionality of drug colors cannot be swept away on the ground that the initial color selection was arbitrary and any color could have been used, although that is precisely the position taken in many of the recent decisions. It seems highly unlikely that the same logic would be applied to a traffic light or a fire engine although the initial selection of their colors was also a matter of arbitrary choice.

The Second Circuit opinion does not and could not wholly refute the clear factual findings regarding functionaltiy but, rather, concludes that it is preferable to have the medical and pharmaceutical communities reeducate patients who suffer confusion or anxiety as a result of purchasing a lower cost generic drug of a different color rather than to permit Petitioners to continue selling an identically colored product.[23] In reaching this conclusion, the Second Circuit not only imposes a form of penalty on those who desire to purchase a less expensive prescription drug, but also reverses the balancing of interests defined by the prevalent authorities. As the Court of Customs and Patent Appeals has stated in construing *Kellogg* and a number of other decisions relating to attempts to monopolize product features:

> "The true basis of such holdings is not that they [product features] cannot or do not indicate source to the purchasing public but that there is an overriding public policy of preventing their monopolization, of preserving the public right to copy. A certain amount of purchaser confusion may even be tolerated in order

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[23] Precisely the same logic has been applied in the New Jersey cases. See, e.g., *Boehringer-Ingelheim GmbH* v. *Premo Pharmaceutical Laboratories, supra,* footnote 18.

to give the public the advantages of free competition. *Application of Deister Concentrator Company, Inc.*, 289 F2d 496, 504 (C.C.P.A. 1961).

Insofar as the record is concerned, it is not even established that patients are being asked to tolerate any confusion. No claim is made that the consumers in Respondent Ives' shopping survey received the wrong medication or that patients were unable to determine the identity of the manufacturer of their medication. Rather, the evidence merely shows that the word "Cyclospasmol", in some form, appeared on the label, even though in nine out of the ten instances the patient was informed that a generic substitute was being dispensed. These facts cannot be equated with consumer confusion since, in the unique circumstances under which prescription drugs are dispensed, the patient's primary concern is in receiving the medication which the doctor prescribed, and there is no reason to suppose that the patient knows or really cares about the source of origin of the drug.

On the other hand, the evidence of functionality, even as construed by the Second Circuit, at least establishes that the color of the medication is an important ingredient in free competition in addition to having independent utility. It takes little imagination to recognize that doctors and pharmacists would avoid prescribing or dispensing more than one color of a particular medication in order to conserve their own time rather than the patients' money and to avoid unnecessary confusion or anxiety for older and infirm patients. Moreover, the suggestion that patients can be re-educated to a new color fails to explain how this re-education would work in a practical environment, e.g., when the newly colored medication is dispensed to a hospital patient by a nurse's aide and no doctor or pharmacist is immediately available to reassure the patient that a mistake is not being made. The obvious answer to this dilemma is that a hospital is not likely to stock multiple colors of the same medication, and the Trial Court so found based

on undisputed evidence.[24] The problem which would be caused by dissimilarly colored medications has also been recognized in at least one State substitution law which requires that refill prescriptions be refilled only with the same drug product used to fill the original prescription. *Wisconsin Statutes Annotated* § *450.075(4)*.

All of the foregoing establishes beyond significant doubt that an injunction barring a generic drug manufacturer from distributing an identically colored version of a therapeutically equivalent medication will interfere with free competition with respect to a product on which the patent monopoly has expired. If color is enjoined, generic drug manufacturers will be foreclosed from a substantial segment of the market, both by doctors who veto substitution to avoid a color problem and hospitals which limit purchases to a single color. Such an injunction would contravene this Court's decision in *Kellogg* and the long line of cases which have since applied its compelling logic.

The Second Circuit opinion seeks to minimize the actual impact which an injunction against color would have on competition by noting that some major pharmaceutical companies are now engaged in the manufacture of so-called "branded generics" in colors which differ from the formerly patented medication. The trial record establishes that these products were only recently introduced by these companies as a response to the State substitution laws and sell at a price which is lower than the original medication but significantly higher than the true generic substitutes involved in this litigation. The makers of

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[24] Further evidence of the impact of color on hospital purchases may be found in *Biocraft Laboratories, Inc.* v. *Merck & Co., Inc.*, Civil Action No. 77-693 (District of New Jersey, Memorandum Opinion, October 2, 1980). The evidence considered by the Court in the Motion for Summary Judgment in that case included advertisements and promotional activities by Merck strongly urging that a switch to a differently colored medication would cause confusion of both patients and hospital staff. These ads were designed to frustrate competition from a differently colored medication being offered by another company.

branded generics still employ "detail men" who personally visit doctors and pharmacists for the purpose of persuading them that their higher priced products should be selected as substitutes in those instances where the State substitution law does not require that the lowest price generic drug be substituted. Obviously, only those companies having the sales force and financial resources to engage in the expensive promotion required to gain a foothold in the "branded generics" market and who have well known company names can compete in that fashion.

In relying on the existence of this new type of marketing practice as justifying an injunction against identically colored medications, Respondent Ives places economic barriers on the meaning of free competition which were clearly not contemplated by *Kellogg*. The issue here is not whether it would be possible for a potential new competitor to penetrate the market for a drug product on which the patent had expired by spending enough time and money to create a demand for a generic drug of a different appearance. The issue is solely whether the law requires the newcomer to do so when the appearance of the previously patented product has functional attributes and has not established secondary meaning to patients.

E. The Labeling Requirements of State Substitution Laws Are Sufficient to Guard Against Acts of Unfair Competition

Each of the State substitution laws contains provisions for labeling the prescription container with information with respect to the name of the drug and the source of origin of the drug, and penalties to ensure compliance with these requirements. In the State of New York mislabeling is a misdemeanor, and multiple violations of the labeling requirements will result in fines, imprisonment and the loss of license to engage in dispensing prescription pharmaceuticals.[25] These provisions are being enforced. As the Second Circuit noted (for a different reason), a

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[25] New York Education Law § 6816 (McKinney's 1981 Supp.).

substantial number of indictments have been handed down in the course of enforcement of the New York labeling law.

There is no reason to suppose that there will be widespread violation of these State laws by pharmacists. As this Court noted in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc., supra,* at 768, high professional standards, to a substantial extent, are guaranteed by the close regulation to which pharmacists are subject, and pharmacists who are guilty of professional dereliction that actually endangers their customers will promptly lose their licenses.

The labeling requirements of the New York substitution law are clearly more stringent and carry higher penalties than the type of labeling relief normally accorded in cases of this kind. See *Warner* v. *Lilly, supra,* at 533; *Upjohn Company* v. *Schwartz, supra,* at 262. Moreover, additional labeling possibilities are available. At least one of the present Petitioners has offered to print its name on each capsule and that practice is becoming much more widespread in the generic pharmaceutical industry in those instances where it is possible to do so.[26]

Although the present case does not involve a therapeutically non-equivalent product, such products have been involved in some of the recent cases and, understandably, may have influenced the lower court decisions to enjoin color simulation.[27] However, an injunction against color is not necessary to remove such therapeutically non-equivalent drugs from the market. They are subject to re-

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[26] *Ives Laboratoires, Inc.* v. *Darby Drug Co.,* 455 F.Supp. 939, 941.

[27] In *Beacham, Inc.* v. *Zenith Labs., Inc.,* Civil Action No. 81-1731 (District of New Jersey, Beach Decision, October 22, 1981) the Court denied a preliminary injunction on an identically colored but therapuetically equivalent drug and applied standards with respect to plaintiff's burden of proving secondary meaning which are consistent with the Trial Court's decision in this case.

moval by the FDA. 21 U.S.C. § 355; *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F2d 795 (2d Cir. 1980). Moreover, the distribution of an identically colored medication which is not therapeutically equivalent could be construed as carrying with it a false representation with respect to the nature of the product and, therefore, be subject to an injunction under § 43(a) of the Lanham Act. 15 U.S.C. § 1125(a).

Any or all of the foregoing remedies, or other similar labeling or notice provisions, will clearly serve the purpose of preventing unfair competition while perserving free competition in precisely the fashion contemplated by long-established public policy.

F. Conclusion

This Court is not being asked to legislate a solution to the problems involved in the distribution system for prescription drugs, or to create an exception to the law because of the substantial public interest involved. To the contrary, the proper resolution of this case requires nothing more than the application of the doctrine of *stare decisis* to a consistent line of decisions covering a span of almost a century. In applying that doctrine, this Court will also be giving substantial reinforcement to the policy underlying legislation enacted by the States in their traditional role of protecting the health and welfare of their citizens.

Respectfully submitted,

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DARBY DRUG CO., INC. *et al.*,
Petitioners,

v.

IVES LABORATORIES, INC.,
Respondent.

BRIEF FOR MEDICINE IN THE PUBLIC INTEREST AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

No. 80-2182

DARBY DRUG CO., INC. *et al.*

Petitioners,

v.

IVES LABORATORIES, INC.

Respondent.

BRIEF FOR MEDICINE IN THE PUBLIC INTEREST AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

I. AUTHORITY TO FILE

This Amicus Brief is presented to the Court under Rule 36.2 and letters of consent from the Petitioners and Respondent have been filed with the Clerk of the Court.

II. INTEREST OF AMICUS CURIAE

Medicine in the Public Interest, Inc. (MIPI) is a non-profit, tax exempt corporation organized in the early 1970s for the purpose of conducting studies, performing analyses, and making evaluations of public and private programs and policies affecting health care in the United States.

Through an interdisciplinary approach, reflecting governmental, academic, medical, industrial, and consumer interests, MIPI has acted as a forum for these disparate interests to identify common ground for dealing with the complex issues

involved in drug research and development, review and approval, distribution and related areas. The results of these efforts have yielded several publications,[1] distributed to policy makers and other interested parties throughout the United States.

One of MIPI's publications — *Medical, Legal, and Economic Aspects of Drug Product Selection* (1979) — is particularly relevant to the case before this Court.[2] MIPI's interest and expertise in issues related to drug policy and its concern for the rights and interests of patients affected by such policy led MIPI to bring to this Court's attention, as it interprets the pending trademark and competiton law issues, the need to consider the effects on those most vulnerable to deception and confusion in drug substitution and dispensing — the patient/consumer.[3]

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[1] *Rights and Responsibilities in Drug Research* (1977); *Postmarking Surveillance of Drugs* (1977); *Drug Abuse, Data Systems, and Regulatory Decisions* (1978)

[2] Copies of this publication have been lodged with the Clerk of the Court. See pages 31-34 which contain a discussion of disclosure, informed consent, and "look-alike" drugs. See also the statement of the Food and Drug Administration representative, pages 57-58, which "favor[s] consumers' knowing at all times whenever they have received a substituted product, regardless of how innocuous the drug might be."

[3] MIPI notes the submission of an amicus brief by the American Association of Retired Persons purporting to represent the public interest or at least a portion of it, namely the elderly. In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), AARP also filed an amicus brief. AARP relates in its *Virginia* brief that it operates walk-in pharmacies and is "the largest non-governmental mail order dispenser of prescription drugs," Brief at 2. Thus, AARP has an interest in the present case both on behalf of the elderly and as one of the largest pharmacies. Those interests are frequently mutually exclusive as seen in this case and discussed in MIPI's brief. Furthermore, AARP based on its argument in the *Virginia* brief on the consumers' "right to know," Brief at 6. It is interesting that AARP makes no mention of that right in the present case. Instead, it is MIPI alone that advocates that the public interest is best served by providing patient/consumers, including the elderly, with full disclosure to enable them to exercise their right of informed consent.

III. SUMMARY OF ARGUMENT

Although the issues and arguments before this Court focus on federal trademark law and its effect on competition in the marketing of ethical pharmaceuticals, it is imperative that the rights and interests of the *patient* be fully protected in accordance with the long-established legal principles of full disclosure and informed consent whenever medical professionals — physicians *and pharmacists* — prescribe and dispense a drug. Furthermore, such disclosure guarantees that the patient, as a *consumer*, receives the cost savings to which he is entitled when generic substitution occurs.

Petitioners would have this Court sanction the dispening of substituted drugs without disclosure to the patient and without the patient's corresponding informed consent, essentially on the grounds that anxiety may result if the patient be well informed. This paternalistic approach not only is outmoded, but contradicts the consistent position of the Congress, federal regulatory agencies, and federal courts that informed consent and disclosure to the patient are the cornerstone of the patient-physician/pharmacist relationship. Exceptions for the sake of convenience or speculative concerns about patient anxiety cannot be countenanced as a matter of fact and law.

The patient/consumer must be provided with full disclosure to permit the making of an informed decision as it affects his health interests. Disclosure is also necessary as it affects the resolution of potential products liability claims, as well as the removal of drugs that pose potential health hazards.

The question before the court is not one of economics between generic and brand-name manufacturers. Rather, the fundamental issue is whether patient/consumers will be deprived of protection offered through the time honored mechanism of informed consent and whether they will be deprived of the savings realized from generic substitution. Full disclosure by the physician about the prescribed drug and by the pharmacist,

who in his professional judgment substitutes a generic product, is an absolute, positive, legal obligation to the patient. It cannot be defeated by permitting the use of look-alike drugs to keep the patient/consumer blithely unaware of what has transpired.

MIPI, in its *Drug Product Selection* report referred to previously, summarized the applicable standard at page 2:

> Drug-product selection involves a body of ethical and legal consumer rights. These rights include knowledge that substitution has occurred and an ability to make informed choices about drug products based on information provided by both physicians and pharmacists. *Consumer deception should not be promoted or practiced for any reason.* (Emphasis added).

Petitioners' explicit claim that look-alike drugs are designed to deceive the patient clearly violates this principle. Despite all claims about functionality of color and other technical arguments, the fact remains that the use of the look-alike drugs promotes deception of the patient/consumer in violation of clearly established principles designed to protect him. The tenuous claim of functionality of color cannot be allowed to defeat the patient's right to know and, in turn, enable him to exercise his informed consent.

IV. ARGUMENT

A. The Right To Full Disclosure And Informed Consent Requires That Patient/Consumers Realize That Drugs Being Dispensed Are Generic Substitutes

The consumer's right to know, embodied in the field of medicine by the concept of informed consent, is a long standing principle of American law. This principle is directly applicable to the present case. Petitioners' production and marketing of generic pharmaceuticals so similar in appearance to brand-name products already on the market is a deliberate attempt to mislead the American consumer, and preclude the American patient from exercising his right of informed consent. The

process of generic drug substitution gives consumers a choice and that choice should not be thwarted by pharmaceutical products identical or so nearly identical in appearance that consumers cannot distinguish between them.

In *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), this Court found

> So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. *It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed.* To this end, the free flow of commercial information is indispensable.

425 U.S. at 764 (Emphasis added). Intelligent and well informed decisions on drug purchases can be made by consumers only if they realize and understand that they are receiving a generic substitute.

The concepts of informed consent and right to know have been traditionally applied where a patient is receiving medical care. The concepts have developed over the years to the point where patients today have a right to be told and to understand the medical process to which they are to be subjected. *See, Cunningham* v. *Yankton Clinic*, 262 N.W.2d 508 (S.D. 1978) for a development of the informed consent doctrine. These concepts have consistently been noted and accepted without question, *Rush* v. *Miller*, 648 F.2d 1075, 1076 (6th Cir. 1981); *Lambert* v. *Park*, 597 F.2d 236, 238-239 (10th Cir. 1979); *Henderson* v. *Milolsky*, 595 F.2d 654, 656-657 (D.C. Cir 1978); *Dewes* v. *Indian Health Service*, 504 F.Supp. 203, 206-207 (D.S.D. 1980); *Margaret S.* v. *Edwards*, 488 F.Supp. 181, 206-208 (E.D. La. 1980) and *Hitchcock* v. *United States*, 479 F.Supp. 65, 78 (D.D.C. 1979).

Similar requirements are mandated by a variety of Federal regulations, including those for human experimentation gener-

ally and drug testing in humans specifically. The regulations of both the Department of Health and Human Services, 45 CFR 46, and of the Food and Drug Administration, 21 CFR 50 *et seq.*, strongly mandate that all human subjects be fully informed before they make any decisions affecting their medical future. The principles of informed consent developed in research settings are equally applicable to medical practice. *See* R. Levine, M.D., *Ethics and Regulation of Clinical Research* (1981), at 93-95. It is inconceivable that Petitioners argue for a lesser standard for the dispensing of drugs to patient/consumers.

B. Patient/Consumers Are Not Being Informed That Generic Substitutes Are Being Dispensed By Pharmacists

The record in this case is replete with examples of mislabeling by pharmacists filling prescriptions with generic cyclandelate. The opinion of the Second Circuit in the case below noted that an impartial test shopping demonstrated that 29% of the pharmacists shopped mislabeled generic cyclandelate as Cyclospasmol, *Ives Laboratories* v. *Darby Drug Co.*, 638 F.2d 538, 453 (2nd Cir. 1981). It is reasonable to assume that pharmacists, who either intentionally or mistakenly mislabel generics as brand-names, are unlikely to disclose the fact that a generic has been substituted for the prescribed drug.

Passing off generic look-alike substitutes as brand-name pharmaceuticals, either intentionally or inadvertantly, is not limited to this case. In *SKF* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3rd Cir. 1980), the Third Circuit recounted a study showing a 4% unlawful substitution rate and a 23% illegal mislabeling rate for two other drugs, 625 F.2d at 1059. *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157, 158 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 766 (3rd Cir. 1978) likewise noted widespread passing off and in *Hoffmann-LaRoche Inc.* v. *Premo Laboratories, Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980)

the District Court calculated that mislabeling occurred 43% of the time in a field study, 210 U.S.P.Q. at 380.

In *Pennwalt* v. *Zenith Laboratories, Inc.*, 472 F.Supp. 413 (E.D. Mich. 1979), the court wrote:

> If, as a practical matter, substitutions cannot be detected, it is a short step from passing the savings on to the consumer to passing the savings on to oneself.

472 F.Supp. at 420. The District Court found examples of pharmacists doing just that. The clear, obvious, most effective way to prevent such chicanery is to require that both brand-name drugs and generic substitutes have readily apparent and distinguishable appearances.

A recent survey found that 23% of the time (67 out of 238) pharmacists either failed to properly substitute generic drugs or dispensed generic drugs but charged the same or higher prices as the comparable brand-name drugs, *Report of [New York State] Attorney General Robert Abrams and [New York City] Consumer Affairs Commissioner Bruce Ratner on New York Generic Substitution Law* (1979), p.10.

These results confirmed those of an earlier New York study which found that of thirty pharmacists, randomly surveyed, thirteen violated the New York substitution law. This "mistake rate" of 43% no doubt influenced the directors of the study who noted that "the study shows that comparison shopping is essential to obtain prescription drugs most economically." The New York City Department of Consumer Affairs, *Comparative Drug Prices and Compliance with the Generic Drug Substitution Law in New York City: An Empirical Study* (1978), pp. 2, 5-7. Comparison shopping can be done only if patients can distinguish between products and can make an informed decision as to which they wish to purchase.

It is unrealistic to expect consumers to inquire about the availability or prices of substitutes if they have no idea that

substitutes are available or are being dispensed. Many patients are unaware of substitution laws in general or may not realize they are applicable to a particular prescription. In 1979, the Federal Trade Commission's Bureau of Consumer Protection published a staff report, *Drug Product Selection*, that focused on generic substitution laws. The report noted that substitution laws in general envisioned patient participation and decision-making but that some consumers were unaware of substitution laws, at 168, 191. The FTC report contained the "Model Drug Product Selection Act" which included a requirement that consumers be notified by pharmacists when substitution occurs and be told of their right to refuse the generic substitute, at 279.

Consumers are entitled to be informed by pharmacists that a substitute is being dispensed in order that they may make an intelligent, informed choice, since

> Caveat emptor is not the norm for the consumer of medical services. Duty to disclose is more than a call to speak merely at the patient's request, or merely to answer the patient's questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision.

Canterbury v. *Spence*, 464 F.2d 722, 783, n.36, (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). The requirement that pharmacists disclose substitution, coupled with a ruling that generics be unambiguously distinguishable in appearance from the brand-name product, will guarantee achievement of the goals of (1) substitution to foster savings for consumers, and (2) informed consent to protect patients.

Of further concern to consumers is the practice of some pharmacists to provide generic substitutes when the physician has specified that the brand-name drug be provided. The record demonstrates instances of such conduct and the Second Circuit noted undisputed evidence "suggesting that illegal substitution and mislabeling in New York are neither de minimus nor inadvertent," 638 F.2d at 544. The Second Circuit was no doubt

influenced by Respondent's evidence of fifteen instances of illegal substitution of generic cyclandelate for Cyclospasmol, *Id.* at 543, and the six New York City indictments for the same offense, *Id.* at 544.

The fact that disclosure is not being made is attributable not only to pharmacists but also to Petitioners' use of visually identical products. The Second Circuit properly held that generic manufacturers may not provide the means to encourage deception where they could "reasonably anticipate" that deception would occur, 638 F.2d at 543. This holding is fully consistent with traditional interpretations of trademark law. As this Court stated long ago:

> A man is not to sell his own goods under the pretense that they are the goods of another man; he cannot be permitted to practice such a deception, *nor to use the means which contribute to that end.*

Hanover Star Milling Co. v. *Metcalf,* 240 U.S. 403, 413-414 (1916) (Emphasis added).

C. Petitioners' Use Of "Look-Alikes" Is Designed To Deceive Patient/Consumers To The Detriment Of Their Legitimate Economic And Health Interests

Petitioners have deliberately attempted to mislead the American public. They readily admit that they intend their products to be identical, or nearly identical, in appearance as Cyclospasmol. The distinctive color of Cyclospasmol was not determined by the raw materials, but rather was chosen by the manufacturer. Petitioners have marketed their generic cyclandelate with identical colors, even though there was nothing to prevent them from choosing a myriad of other colors to distinctly identify their own generic products.

Petitioners originally did not even mark their capsules with their name or identification number but rather left them blank, thereby further adding to the confusion and misidentification.

Since this action was initiated, two of the Petitioners, Premo and Inwood, have begun to label capsules with their identification. *See* the Second Circuit opinion, 638 F.2d at 540, n.4. However, drug identification names and numbers are imprinted in very small type. It is totally unrealistic to expect patient/consumers to differentiate between apparently identical products on the basis of some very "fine print" on the capsule.

Furthermore, in perhaps the most glaring example of deception, one of the Petitioners, Sherry Laboratories, originally marketed its generic cyclandelate as Spasmol, an obvious attempt to capitalize on Respondent's trade name Cyclospasmol. This is but the most extreme example of a consistent, continued attempt by Petitioners to deny the American consumer the right to make an informed decision as to which pharmaceutical product to purchase and which to ingest pursuant to a prescribed medical regimen.

Such activities by some of the Petitioners are not limited to the cyclandelates involved in this case. Prior activities by some of the Petitioners have left a trail of deliberate confusion, copying of pre-existing products, and patent infringement. *See, e.g., SKF* v. *Premo Pharmaceutical Laboratories, Inc., supra,* and cases cited therein, 625 F.2d at 1058, n.1; *A.H. Robins Co.* v. *Medicine Chest Corp.*, 206 U.S.P.Q. 1015 (E.D.Mo. 1980) (Petitioner Inwood Laboratories); and *Hoffmann-LaRoche, Inc.* v. *Premo Pharmaceutical Laboratories, Inc., supra,* and cases cited therein, 210 U.S.P.Q. at 378.

Petitioners' justification for deceiving the consumer is based on an outmoded, paternalistic theory that the consumer is actually better off being deceived. Petitioners argue that patients receiving generic drugs different in appearance from brand-names that they have been using would refuse to take the generics. Petitioners attempt to paint a sorry picture of bewildered patients, anxious consumers, all unable to grasp the simple fact that the equivalent pharmaceutical ingredients may

be contained in different color capsules. Petitioners appear to suggest that the elderly, all of whom Petitioners appear to assume are in advanced stages of senility, are particularly prone to confusion and anxiety and would refuse to take a different colored drug.

American consumers, especially those over sixty, are not the fools Petitioners would have this Court believe. The consumers of this country are fully capable of understanding that the same product may come in different packages and are able to make informed, reasoned decisions as to which product they wish to purchase, based on their confidence in the manufacturer and on the price of the product. The notion that the elderly are unable to make informed medical decisions has been repeatedly rejected by leading authorities and studies. For a review of such authority see Ostfeld, "Older Research Subjects: Not Homogenous, Not Especially Vulnerable," *IRB: A Review of Human Subjects Research*, Vol. II, No. 8 (1980), at 7, and "National Institute on Aging: Protection of Elderly Research Subjects", DHEW Publication 79-1801 (1979).

If indeed some patients do not take their medicine regularly, there are many factors affecting compliance, the least of which is the color, size, or shape of the capsule. The key factor in patient compliance is the doctor-patient relationship supplemented by the pharmacist-patient relationship. A patient who is informed, knowledgeable and encouraged to take medicine will do so regardless of the appearance of the pill if he believes it is in his best medical interest. The frequency of medication and the number of drugs may also affect compliance, but again the crucial element is explanation by the physician or pharmacist, not deception or confusion by the color, size, or shape of the capsules or tablets involved.

Similarly, the condition of the patient may affect compliance. Sick patients obviously have more problems in complying than relatively healthy ones. Both costs and confidence

in the medication can determine whether drugs are purchased and then used. The cost factor problem can be reduced by identifying generics so that the consumers will know they are getting substitutes and accordingly can shop for and demand the best price.

The Petitioners' justification for identically-colored, look-alike cyclandelate capsules was considered by the Second Circuit, which found:

> Their argument that look-alike capsules reduce patient confusion or anxiety in taking medication enable doctors to communicate with patients more easily concerning their medication, and aid in their identification of the drug in an emergency situation, are unconvincing. Although a few doctors and one pharmacist were of the view that patients receiving capsules in a size, shape or color different from the medication they usually receive may at first believe that they have the wrong drug, there was no evidence of any instances of such confusion, much less that it was widespread, or that it could not easily be cured by explaining the change to the patient, either voluntarily in accordance with accepted professional practice or in response to the patient's inquiry.

638 F.2d at 544.

Furthermore, in reviewing the evidence the Second Circuit noted:

> Indeed one witness called by appellants (Lawler) testified that when the doctor or the druggist explains that the different color or differently shaped capsules are the same generic drug, patients do not refuse to accept and use it. There was no evidence that doctors or druggists refused to furnish such explanations. No patient testified to confusion or anxiety. Nor did appellees offer any survey of the patients' attitudes with respect to the matter.

638 F.2d at 544-545. Petitioners' contention that look-alikes are needed to eliminate patient anxiety and confusion are directly rebutted by those state substitution laws which require man-

datory disclosure of generic substitution. *See e.g.*, Fla. Stat. Ann. § 465.25 (1981); Ky. Rev. Stat. § 217.822 (1980); Vt. Stat. Ann. tit. 18 § 4605 (1980); and Wis. Stat. Ann. § 450.075 (1980). Such laws clearly intend that pharmacists disclose that a generic has been substituted, in direct contradiction of Petitioners' arguments that patients should not discover or be advised that they are receiving a generic substitute.

Furthermore, Petitioners fail to present any indication that patients want to be deceived. Logic dictates that consumers wish to know which medication they are receiving. They can then make an informed decision as to which pharmaceutical product they wish to purchase and that decision may be based on their perception of the reliability of the manufacturer, the relative cost of the products, or whatever other criteria on which they may base their decision. Patients cannot make that decision unless they can distinguish between products. A recent research poll taken by Cambridge (Massachusetts) Reports, Inc. revealed that 90% of the consumers surveyed believed it important to know if a generic substitute had been dispensed. Of those individuals, 25% felt that the use of look-alikes would cause confusion. *America's Health*, Vol. III, No 1, Spring, 1981, at 15.

Petitioners simply have not proved their argument because it is without merit. Patients are better off being informed, not deceived. Consumers are in a stronger position when they are given all the facts rather than having the truth withheld from them. If Petitioners believe that "patient anxiety" should entitle them to delude consumers into believing that generics are actually brand-names, then a logical extension of their argument is that they be allowed to imprint Ives' name and identification number on their capsules.

There is yet another reason why look-alikes may be detrimental to the consumer. Sometimes, fortunately very rarely, a pharmaceutical is improperly manufactured or handled and may become adulterated.

Should such an event occur, accountability and identification become critical factors. Should a drug produce harmful effects, it is vital that the offending product be identified not only so that the injured consumer might have recourse against the manufacturer, but also so that health agencies can identify the pharmaceutical, pin-point its maker and remove it from the market. The existence of a plethora of capsules all identical or nearly identical in appearance, manufactured by different companies, complicates that process, placing the public health at risk.

A similar situation could arise if a product is not effective. Assume a physician prescribed Cyclospasmol and the pharmacist substituted a generic look-alike. Assume that the look-alike was either adulterated or perhaps was not effective. The patient, not knowing he or she had received a substitute, would report that the drug was not working and the physician might well then assume that cyclandelate was not the proper medication. In such a situation, it is important that there be accurate product manufacture identification, so that the consumer and physician are able to distinguish between manufacturers of similar products.

In *SKF* v. *Premo Pharmaceutical Laboratories, Inc., supra,* the Third Circuit considered this question and the concern it voiced is applicable to this case. The court noted that any patient or physician dissatisfaction would naturally be directed toward the long-standing brand-name manufacturer and that any suit would be filed against the "deep pocket defendant." The Third Circuit wrote:

> the striking similarity in appearance of the two products would make it entirely unlikely [the brand-name company] could prove that the harm was cause instead by [generic] capsules, because the only proof as to the source would be the capsules, long since digested by the patient.

625 F.2d at 1066.

This concern also extends to the consumer. If a patient knows that he purchased only a "blue capsule," he might well not know which manufacturer(s) to sue, particularly if the capsules had long since been digested. Litigants who have been unable to identify the precise manufacturer of an allegedly defective drug have not fared well in court, their cases having been dismissed. *See, e.g. Ryan* v. *Eli Lilly Co.*, 514 F.Supp. 1004 (D.S.C. 1981) and cases cited therein. Thus, this Court can insure that consumers retain the practical right to sue the maker of a defective drug by rejecting Petitioners' contention that they be allowed to market drugs so similar to a pre-existing drug that confusion and deception result.

There is little reason why Petitioners cannot manufacture generic substitutes in capsules different in appearance and color from Respondents. In *Hoffmann-LaRoche, Inc.* v. *Premo Pharmaceutical Laboratories, Inc., supra*, the District Court related that two major capsules manufacturers, Elanco Products and Parke-Davis, had, respectively, 40 and 43 different colors available for capsules. Assuming the capsules often come in two colors, the Court calculated that there were 1,600 or 1,849 possible combinations available, 210 U.S.P.Q. at 381. In *Marion Laboratories, Inc.* v. *Michigan Pharmacal Corp.*, 338 F.Supp. 762, 768 (E.D. Mich. 1972), *aff'd mem.*, 473 F.2d 910 (6th Cir. 1973), the court noted that there appeared to be as many as 12,000 color combinations available. Surely one or more of those combinations might be used by Petitioners.

D. The Only Acceptable, Effective Method To Ensure That Patients/Consumers Are Well Informed About Generic Substitutes Is To Require That They Are Visually Distinguishable.

Various parties before the Court in this case have suggested a variety of means by which the consumer might be informed that a generic substitute has been dispensed. Implicit in these suggestions is a recognition that consumers must be informed and that competing drug products must be clearly distinguishable from each other.

Petitioner Premo suggests that, at most, the manufacturers or distributors of generic substitutes be required to label bottles containing their products in such a way that pharmacists purchasing them are warned not to dispense them in violation of state substitution laws and not to mislabel them as Cyclospasmol, Brief at 33. Such a suggestion is virtually meaningless. The District Court opinion below, *Ives Laboratories Inc.* v. *Darby Drug Co., Inc.*, 488 F.Supp. 394 (E.D.N.Y. 1980), commented that such a requirement "would not be useful" because pharmacists are already aware of the difference between the brand name product and the generic substitute, 488 F.Supp. at 398. Any pharmacist who violates a state substitution law will do so regardless of such labels. It is still the consumer who needs to be informed, not the pharmacist.

The State of New York, as Amicus Curiae, offers a different alternative. The State suggests that generic substitutes be required to contain a logo or imprint in a contrasting color so as to be readily visible, Brief at 7. This possibility was considered and rejected by the District Court, *supra*, and by the Third Circuit in *SKF* v. *Premo Laboratories, Inc., supra*. This fine print goes unnoticed by most consumers and those with poor eyesight are unable to even read it. In *SKF* v. *Premo Pharmaceutical Laboratories, Inc.*, the Third Circuit noted that such identification is "decipherable only with great difficulty," 625 F.2d at 1061. The District Court originally hearing this case also considered this question and concluded "nor would it be fruitful to require all defendants to print their names on the capsules. The evidence showed that the capsules are so small that such an imprint would be of little, if any, value," 488 F.Supp. at 398. Consumers are thus best informed that products are different when they have distinct differences in appearance, such as color, size, or shape, and not when they have only the minor variations caused by tiny type face.

The United States, as Amicus Curiae, suggests another possibility — that generic manufacturers prepackage their products

with their own labels for resale to consumers. Thus, the pharmacist would not rebottle or repackage the product. While this idea has some merit in that it would help identify the product involved, it presents significant practical problems. The number of pills to be dispensed in any given prescription varies widely. Thus to comply with this requirement a pharmacist would have to have on hand, for example, prepackaged bottles containing, respectively, 10 capsules of each generic, 15 capsules of each generic, 20 capsules of each generic, 25 capsules of each generic, and so on. Such a requirement would be unworkable and would be detrimental to the patient. Pharmacists buy in bulk and then rebottle. It would be more costly to purchase prepackaged bottles and this increased cost would ultimately be borne by the consumer. Furthermore, logistical problems of stocking the large number of prepackaged bottles might deter pharmacists from carrying generics, thus lessening the options available to the consumer.

None of these proposed solutions are adequate to remedy the core issue of providing patient/consumers with full disclosure to enable them to realize savings from substituted generics and to protect their health and welfare through informed consent. In fact, the only effective means available to protect the patient/consumer demands that the competing drug products be unambiguously distinguishable by color, shape, and size.[4]

There is a dramatic need for easily recognizable, distinguishing characteristics to differentiate generics from the brand-name products. If a patient has been purchasing, for example, pale blue capsules of a given size for a particular condition, he

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[4] Amicus Curiae notes with approval the recent resolution adopted by the Board of Directors of the Health Insurance Association of America. In its 1 November, 1981, Position Statement on Generic Drugs the Directors resolved that "The HIAA opposes any practice with respect to the manufacturing and dispensing of drugs which could lead to confusion or deception of consumers."

will be alerted that a generic is being substituted if he receives dark green capsules of a different shape the next time the prescription is filled. The difference in color, size, and shape serves to notify the patient that a change has occurred. The consumer may wish to request that the brand-name be dispensed or the consumer may wish to comparison shop to determine which pharmacist offers the best price savings for the generic substitute. By the use of visually distinguishable substitutes, it is the consumer who makes the choice, not the manufacturer or the pharmacist.

Petitioners' argument that economic necessity forces them to copy, confuse and deceive should fall upon deaf ears. Many generic producers manufacture their products in capsules totally dissimilar from the pre-existing brand-name pharmaceutical. In *SKF* v. *Premo Pharmaceutical Laboratories, Inc., supra,* the Third Circuit found that while many generic companies produce look-alikes, an equal number market products that are not similar to the brand-names, 625 F.2d at 1060, n.3. In the opinion below, the Second Circuit noted that many generic drugs are successfully marketed without copying other products and cited the generic cyclandelate manufactured by the W. E. Hauck Company as an example, 638 F.2d at 545. In fact, the competitive system engendered by the substitution laws ensures that generics are given every advantage to compete. The resort to consumer deception, under the rubric of competition, is unsupportable and must not be allowed to override the much more substantial interest of patient/consumers to be well informed and to realize the cost savings from generic substitutions. *Pharmaceutical Society of the State of New York* v. *Lefkowitz,* 586, F.2d 953 (2nd Cir. 1978).

V. CONCLUSION

The core of Petitioners' case is that they should be allowed to practice deception. They admit that they deliberately attempt to confuse the American public. They argue that patients are really

better off not knowing what drug they are paying for and that look-alike substitutes actually perform a public service by deluding consumers.

Such arguments are nonsense and should be rejected out of hand. Patients have the right to know what choices are available to them and have the right to make informed decisions. As this Court succinctly said in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc., supra*, "people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them," 425 U.S. at 770.

For the foregoing reasons, Medicine in the Public Interest respectfully requests that this Court uphold the decision of the United States Court of Appeals for the Second Circuit.

Respectfully Submitted,

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INWOOD LABORATORIES, INC. and PREMO PHARMACEUTICAL LABORATORIES, INC.,

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On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, INC.

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No. 81-11
No. 80-2182

In The

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC., and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, INC.

INTRODUCTION

The National Association of Pharmaceutical Manufacturers, Inc. ("NAPM"), respectfully submits this *amicus curiae* brief in support of petitioners in the captioned matter. A letter of consent signed by all parties to this petition has been filed with the Clerk of the Court.

NAPM is a national trade association representing more than 100 manufacturers and distributors of prescription and "over-the-counter" pharmaceutical products throughout the United States. For many years, NAPM has been the leading national spokesperson for what is commonly known as the generic drug industry. NAPM has represented the industry in the courts both as a party and as an *amicus*. It has appeared before administrative tribunals. It has also appeared in hearings before Congress and the legislatures of numerous states. The petitioners herein, Inwood Laboratories, Inc. ("Inwood") and Premo Pharmaceutical Laboratories, Inc. ("Premo"), are members of NAPM.[1]

This brief discusses the wide-ranging impact that the decision below will have on both the generic drug industry and the public at large. As we shall show, that decision deals a decisive blow against competition and lower drug prices.

ARGUMENT

I.

THE DECISION BELOW IS CONTRARY TO A LONG-ACCEPTED, LEGAL AND NECESSARY INDUSTRY PRACTICE

Do the colors of a drug product remain forever the exclusive property of the patent holder after the patent expires? The Second Circuit says they do, and we assert that that is not, and should not be, the law.

We respectfully submit that what this case concerns is the right of generic drug manufacturers to effectively compete in the

1. The law firm of NAPM's General Counsel also represents Inwood.

market. The real issue presented in this controversy is dollars. Generic companies have proven that they can deliver equivalent products at a fraction of the "brand-name" companies' prices.

It is no accident that this case was filed by Ives on the eve of New York State's enactment of a generic drug substitution law. The efforts to stop such legislation — legislation which gave an imprimatur to the public interest in obtaining lower-priced generic drug products — failed. Other concerted efforts to thwart generic drug sales continue. We submit that this case is one of those efforts.

For the reasons set forth below, and for those contained in the brief of petitioner Inwood, we respectfully submit that the decision below conflicts with the public interest and the law. The decision contravenes an accepted and legal marketing practice which has existed from the inception of this industry. Its inevitable result is a further concentration of economic power in an already concentrated industry. Most importantly, the decision seriously impairs the generic industry's ability to deliver essential medications to fixed-income citizens and governmental agencies at an affordable cost.

A. The Functional Role of Color in the Manufacture and Sale of Pharmaceutical Products

The courts cannot be color-blind. Color is a force. It is a potent force to move people and to make people act. This may arise inherently from the color itself or it may be an acquired effect as a result of experience. A color may thus create a calm effect, a good reaction or a negative reaction. As an example of an acquired effect, we know that butter is identified as a yellow product. Most people would not pick up a stick of butter from a supermarket shelf if it looked green.

Color is a science. Extensive scientific research has been done in the field of color and its effect on man's behavior. It has been found, for example, that a pinkish color will have a tranquilizing effect to reduce agressive behavior and potential violence.[2] It is significant that, in contrast to all of the statements that choice of color is a random decision, the major drug companies are treating color as a science. One of the major pharmaceutical companies, Parke-Davis, conducted an extensive investigation into the use of color in pharmaceutical products.[3] It reported that:

> "[N]umerous investigations in the U.S., England and Continental Europe have established that patients show preferences — and aversions — to various colors. Often these reactions reflect the state of mind of the patients due to their particular ailments."

The importance of color in marketing is undisputed. Color is big business. Large sums of money are expended for color additives to be used in foods, drugs and cosmetics. Extensive market surveys are conducted, and companies spend a great deal of money and time in order to obtain approval from the Food and Drug Administration ("FDA") for such colors. All of this effort is expended for the purpose of finding the most effective marketing color for the specific product.

With a new understanding of the role of color, the major pharmaceutical companies have completely reversed their

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2. Schauss, "Tranquilizing Effect of Color Reduces Aggressive Behavior and Potential Violence", 8 *J. Orthomolecular Psychiatry* 218 (1979).

3. "Capsule Color Considerations" and "The Hard Gelatin Capsule - A Contribution to Drug Safety" (Parke-Davis Division of Warner-Lambert Co. 1980) [newsletter and accompanying advertising circular] [hereinafter referred to as "Parke-Davis Study"].

position in recent years. Years ago, these same companies requested that the government make color, size and shape required specifications for government bids. That request has been discarded. The large brand-name manufacturers are now trying to prevent the generic manufacturers from using the same colors for generic products.

The brand-name company has a period of seventeen years in which to use a specific color for its product. During that time, the product is the only one being marketed. Color over that seventeen-year period develops important functional attributes. Those attributes should not serve as the excuse for extending a seventeen-year patent into one in perpetuity.

Set forth below are several of the well-recognized functional attributes of color:

1. Patient Anxiety and Acceptance

It is a recognized fact that persons using prescription drugs are reluctant to accept products which bear a different appearance. This is particularly true in the case of patients who take drugs over a long period of time. Such a patient may believe that the non-conforming, generic equivalent is different, that it is a mistake in his/her prescription, or that it is less efficacious. The study conducted by Parke-Davis specifically found that colors are associated with the physiological effects of the drugs.

The district court summarized the evidence relating to the question of functionality and concluded that:

> "[M]any elderly patients associate the appearance of their medication with its therapeutic effect. . . . When patients associate the drug with

> its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage." (Pet.App. 63a)

The Second Circuit nevertheless labelled this evidence "unconvincing" and found that there was no evidence that the anxiety "could not easily be cured by explaining the change to the patient." This suggestion flatly contradicts Judge Nickerson's factual finding that:

> "There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors." (*Id.*)

It can thus be seen that if different colors must be used by generic manufacturers, a major effort will have to be made to overcome the patient's belief that there is something wrong with the drug. In addition, as noted above, even those efforts can never be completely successful, for many patients will never be convinced.

2. Confusion by Patients

As Judge Nickerson noted:

> "[S]ome patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. One doctor testified that he prepared a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs." (*Id.*)

This is particularly true for elderly persons who use multiple medications for daily use. Many patients place their daily pills in a carrying case, thereby comingling an assortment of drugs. The only source of identification would then be color, as, for example, in the "red heart pill." This conclusion is buttressed by the fact that many elderly citizens have impaired eyesight, obviating the value of any tiny imprinted marks.

3. Confusion as to Drug Identification

Another key functional aspect of color is its role in identification. As the Parke-Davis Study notes:

> "With more than 50,000 pharmaceutical specialties on the market, quick, accurate identification of one specific medication is of critical importance. . ."

The trial court made such a finding with respect to emergency situations. Hospital emergency rooms are often confronted with unidentified or partially-ingested drugs in an unconscious victim. Color is, as Parke-Davis notes, the most effective means for distinguishing among drugs:

> "An improvement in the safety of drugs is a matter of utmost urgency. . . .Fifty percent of the doctors questioned considered the risk of drug confusion to be great or very great. Eighty-four percent of the doctors thought that on account of this, drugs should be easier to identify by their appearance."
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> * * *
>
> "The doctors were of the opinion that this could best be achieved by the use of color. That this

> opinion is a valid one is confirmed by an observation made on patients: when asked to say what they remembered about a medicine, practically all of them described it by its color."

Aids in identification are important in other hospital situations as well. Nurses administering a series of drugs to patients on a hospital floor usually put several drugs in each of numerous cups. The possibility for confusion is obviously great. Even imprinted identification numbers are of far less efficacy here than easy-to-identify colors. And where a single drug must be sold in several different colors the possibility of confusion is multiplied.

4. Psychological Effects of Color

In addition to other functional characteristics, color also speaks in psychological effects and motivations. Interestingly, that effect is reported by Parke-Davis, one of the brand-name companies:

> "A capsule which, through its color(s) conveys psychologically that it will be beneficial, builds patient confidence in the preparation. This leads to better patient compliance."

A similar finding as to color's psychological impact was reached in a recent article by the Director of the Institute for Biosocial Research.[4]

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4. Schauss, "Tranquilizing Effect of Color Reduces Aggressive Behavior and Potential Violence", 8 *J. Orthomolecular Psychiatry* 218 (1979).

Color is an essential element in the marketing of pharmaceutical products. Without equal access to the marketplace, generic pharmaceutical manufacturers are seriously hindered in their effort to bring lower-priced drugs to the public.

B. The Campaign Against Generic Drug Use

The drug industry has sales in excess of eight billion dollars annually. The large brand-name companies which control the industry charge 100%, 200% and, in some cases, even 400% more than do the generic manufacturers for the same products.

The propaganda for use of brand-name drugs is begun early in the physician's career. From his or her first year in medical school, the student receives free stethoscopes and other materials bearing these brand names. Huge promotional budgets underwrite student visits to the manufacturing plants. Once in practice, a doctor is deluged with prescription pads and other paraphernalia subliminally reinforcing use of the brand-name drug.

The influence of the huge multinational drug companies is enormous, and that influence extends into many spheres. Tremendous efforts have been made, for example, to frighten pharmacists and physicians through the use of "scare advertising," and to prevent the passage of pro-generic legislation. The object, once again, has been to thwart the sale of lower-priced, equivalent generic drugs.

This concerted effort by the large manufacturers did not accomplish its immediate objective, which was to stop passage of generic drug substitution laws. These companies, primarily through the Pharmaceutical Manufacturers Association ("PMA"), have spent millions of dollars in lobbying against a

panoply of measures which proposed to stimulate competition in the marketplace. Strong lobbying in numerous states was directed against legislation requiring posting of prescription drug prices in pharmacies, legislation requiring substitution of lower-priced drugs, regulations requiring a state to purchase generic drugs, and other measures which meant a lower cost to the public and to governmental purchasing agencies.

In conjunction with these efforts a misleading study was prepared. This study, sponsored by one PMA member, claimed significant differences in the quality of generic, as opposed to brand-name, drugs. The Commissioner of the FDA attacked the study, publicly pointing out that the conclusions were incorrect and that relevant data had been misused.

A spate of lawsuits then ensued in lock-step fashion. A number of the large companies brought "color lawsuits" against the same handful of generic manufacturers. These smaller manufacturers simply could not afford the defense costs of several protracted patent and trademark cases.

The "color cases" yielded conflicting and often one-sided results. As one legal commentator notes about decisions in this area:

> ". . . Something may be going on in these cases that is not reflected in the lines of the courts' published opinions. To predict these judgments is now simple, for the same side always wins. To understand the judgments, perhaps, use of a different discipline is required." Stern, "The Persantine, Librax & Elavil Decisions:

Colourful Brands of Drugs," 2 *Eur. Intel. Prop. Rev.* 59 (1981).[5]

More recently, some of the large PMA companies teamed up in a series of court actions in various parts of the country. At issue was the FDA's "paper NDA" policy, which facilitated the approval of generic drugs. As soon as one case was lost in the District of Columbia,[6] the same case was brought in Raleigh, North Carolina.[7] As soon as that case was lost, the same case was brought in Chicago.[8] That case lost as well. Although these efforts were not successful, a one-year delay was accomplished.

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5. Some decisions in England have recognized the need for the use of identically-colored capsules. *See, e.g., Roche Products Ltd. v. Berk Pharmaceuticals Ltd.*, [1973] RPC 473 (Supreme Court of Judicature); *Boots Co. Ltd. v. Approved Prescription Services, Ltd.*, [1980] ___ Ch. ___ B.No. 140 (Unreported: Martin Meredith) (Ch. Div. March 6, 1980), *aff'd*, [1980] B.No. 140 (Unreported: Association) (Court of Appeal Civ. Div. March 28, 1980).

6. *Hoffman-La Roche, Inc. v. Harris*, 484 F. Supp. 58 (D.D.C. 1979).

7. *Burroughs Wellcome Co. v. Schweiker*, 649 F. 2d 221 (4th Cir. 1981).

8. *American Critical Care, div. of American Hospital Supply Corp. v. Schweiker*, [CCH] Food, Drug, Cosmetic L. Rptr. ¶ 38,110 (N.D. Ill. May 13, 1981).

II.

THE DECISION BELOW IS CONTRARY TO THE IMPORTANT PUBLIC INTEREST IN LOWER-PRICED DRUGS AND EFFECTIVE COMPETITION IN THE PHARMACEUTICAL INDUSTRY

If the generic manufacturers can no longer comparatively advertise their products, and if they can no longer provide the color coding that the market demands, their ability to compete will have been seriously impaired. That has been the object of the large brand-name companies, and is the effect of the Second Circuit's decision.

The competing interests in this case can be easily delineated. The large brand-name companies assert an interest in the perpetual extension of their patent monopolies after the expiration of the seventeen-year protection. This translates into continued monopoly prices for those drug products.

The generic industry supports the public interest in lower-priced drugs and in the competitive presence of small businesses in this country. Pharmaceutical products are necessities, not luxuries, for a large part of the population (particularly the elderly). Fixed-income citizens are often forced to choose between exorbitantly-priced drugs and money for meals. One of the two must suffer. As Justice Blackmun said in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976):

> "Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs;

> yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent. Where drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 763-764.

The importance of lower-cost pharmaceuticals extends to governmental purchasing bodies as well. Many state and federal agencies have turned to generic drugs and have recognized significant savings in the process.

In the past ten years, 49 states have enacted "substitution" laws.[9] These statutes reflect the fact that both public citizens

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9. Alabama Code, §34-23-8 (1979); Alaska Stat., §08.80.295 (1976); Arizona Rev. Stat. Ann., §32-1963.01 (1979); Arkansas Stat. Ann., §72-1047-1049 (1976); California (Business and Professions) Code, §§4047.6, 4047.7 (1976); Colorado Rev. Stat., §12-22-124 (1979); Connecticut Gen. Stat. Ann., §§20-185a through 20-185f (1976); Delaware Code Ann., Tit. 24, §2589 (1979); Florida Stat. Ann., §465.025 (1979); Georgia Code Ann., §§79A-408.1 through 79A-408.5 (1977); Hawaii Drug Product Selection Act, Hawaii Rev. Stat., Tit. 19, §§328-91 through 328-99 (1980); Idaho Ann., §§18-479-466, 17-479-460 in acc. with §37-2702(d) (1979) (supplement); Illinois Ann. Stat., ch. 111, §4033 (1977); Iowa Code Ann., §155.37 (1976); Kansas Stat. Ann., §65-1637 (1979); Kentucky Rev. Stat., §217.822 (1976); Louisiana Rev. Stat. Ann., §37-1225 (1979); Maine Rev. Stat. Ann., Tit. 32, §2806 (1975); Maryland (Health) Code Ann., §43-273A (1978); Massachusetts Ann. Laws, ch. 112, §12D (1976); Michigan M.C.L.A., §333.17755 (1978); Minnesota Stat. Ann., §151.21 (1975); Mississippi Code Ann., §§75-29-701 through 75-29-709 (1979); Missouri Drug Product Selection Law, Mo. Ann. Stat., §338.056 (1979); Montana Drug Product Selection Act, Mont. Rev. Codes Ann., §66-1528-66-1536 (1977); Nebraska Drug Product Selection Act, Neb. Rev. Stat., §§71-54.01 through 71-54.08 (1977) (1980 Supp.); Nevada Rev. Stat., §§639.2581 through 639.2599 (1979); New Hampshire Rev. Stat. Ann., ch. 146, §6-b (1973); New Jersey Stat.

(Cont'd)

and state agencies save a great deal of money when they purchase generic drugs.

Substitution laws either permit or require the substitution of lower-priced generic drugs for a brand-name product. In 11 states,[10] the statutes are "mandatory" in that the pharmacist must dispense the lower-priced drug unless the physician insists on having the brand-name product sold. The remaining states have "permissive" statutes, giving the pharmacist the option of dispensing the brand name or generic drug.

Substitution laws stand for recognition of the fact that: (a) generic drugs are therapeutically equivalent to the brand-name products; (b) generic drugs are almost always less costly; and (c) the public interest is best served by legislating substitution.

(Cont'd)

Ann., §§24:6E-6 and 24:6E-7 (1977); New Mexico Stat. Ann., §26-3-3 (1976); New York, ch. 776, Laws of 1977 Reg. Sess.; North Carolina Gen. Stat., §90-76.1-76.6 (1980 Supp.); North Dakota Cent. Code, §19.02.1 - 14.1 (1979); Ohio Rev. Code Ann., §4729.38 (1978); Oklahoma, Tit. 59, §353.21 (1961); Oregon Rev. Stat., §689.515 (1979); Pennsylvania Stat. Ann., Tit. 35, §§960.1 - 960.7 (1976); Rhode Island, Gen. Laws, §5-19-38 (1976); South Carolina Drug Product Selection Act of 1978, Code §§39-24-10 through 39-24-40; South Dakota - Codified Laws Ann., §§36-11-46.1 through 36-11-46.4 (1978); Tennessee - Substitution of Equivalent Drug Product Act, Tenn. Code Ann., §39-2201 (1977); Texas [Health] Code Ann., Tit. 4542a, §12 (1978); Utah - Generic Substitution Act, Utah Code Ann., §§58-17-29 through 58-17-35 (1977); Vermont Stat. Ann., Tit, 18, §4605 (1977); Virginia Code, Tit. 32.1, §§79-87 (1976); Washington Rev. Code Ann., §§69.41.100 through 69.41.180 (1977); West Virginia Code §30-5-12b (1978); Wisconsin Stat. Ann., §140.90 (1976); Wyoming Generic Drug Substitution Act, Wyo. Stat., §§33-24-146 through 33-24-151 (1979).

10. Florida, Kentucky, Massachusetts, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington and West Virginia.

A detailed study of the effect of drug substitution laws was recently conducted by the University of Illinois. The conclusion was that:

> ". . . significant cost savings accrued to consumers when [drug substitution] occurred." Grussing, Purohit, Stewart. "Drug Product Selection in Illinois: An Evaluation of PA 80-976 After One Year of Experience." Summary of Major Findings at 2 (May 30, 1980).

The Illinois study of six other states[11] revealed that significant cost savings resulted in each state when generic drug substitution occurred. *Id.* at 87. The savings ranged from a low of $.86 to a high of $1.92 for each prescription. In 1980, more than 126 million prescriptions were filled in the United States. "The Top 200 Prescription Drugs of 1980", 183 *American Druggist*, 49, 52 (Feb. 1981). The use of generic drugs affords consumers of the nation potential savings of tens of millions of dollars per year.[12]

These substantial savings are jeopardized by the ill-founded decision of the Second Circuit. As Judge Nickerson noted:

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11. Michigan, Wisconsin, Florida, Vermont, Rhode Island and Delaware.

12. On April 10, 1981, the Department of Health for the State of New Jersey announced that its two-year generic drug law saved consumers $6 million. On March 3, 1981, the New Hampshire Council of Aging stated that New Hampshire's then proposed drug substitution law could save the elderly $2 million a year. One month prior, on February 3, 1981, a statewide community organization announced that if Texas adopted a drug substitution law, consumers would save upwards of $30 million. Texas became the 49th state to adopt such a law on May 28, 1981. On June 8, 1981, the New York City Department of Consumer Affairs announced that consumers had paid $12 million unnecessarily for medications because doctors and pharmacists have disregarded the State's generic drug law.

> "[T]he policy expressed in the New York Education Law [is] to encourage legal substitution of lower-priced drugs . . . To require different capsule colors . . . would also severely inhibit legal substitution which the legislature deems to be in the public interest." (Pet.App. 69a)

Nor is there any public interest in granting these already huge companies a virtual monopoly once their products' patents expire. We respectfully submit that there is a sound reason for the seventeen-year limitation on patents. That reason is to prevent monopolies *in perpetuo*, while providing a meaningful incentive for research. Generic competition is healthy and important. It cannot exist without the right to market effectively, a right which the Second Circuit has removed.

III.

THE OPINION OF THE COURT OF APPEALS IS IN ERROR AS TO THE LAW AND THE FACTS

The issue before the Court of Appeals was a fundamental one for this industry. The trial court properly held that generic drug companies were permitted to utilize comparative advertising and identical color combinations in order to compete effectively. That decision was premised upon proof that color serves a valid functional purpose.

We respectfully submit that the opinion of the Second Circuit, which reversed the trial court's findings, contains numerous logical and factual inconsistencies. Examples are set forth below:

1. On the second appeal, the court reaffirmed that the original evidence introduced by Ives as to illegal substitution of cyclandelate would not be sufficient to hold petitioners liable as contributory trademark infringers. The court held, however, that the "additional evidence" showed that in some cases of lawful substitution, the trademark CYCLOSPASMOL was placed by a druggist on the dispensing container. Claiming that such labelling was "widespread", the Court of Appeals held petitioners liable as contributory infringers. The court inexplicably failed to address, however, the threshold question of whether the acts of the pharmacists constituted trademark infringement. The result is that petitioners were held liable for contributory trademark infringement without a judicial finding at any level that trademark infringement, as such, ever occurred.

2. Judge Mansfield acknowledges that contributory trademark infringement requires some intentional suggestion, even if by implication, that the infringer engage in the actions

complained of. The opinion finds implicit suggestion only in catalogs and price sheets which describe the appearance of petitioners' drug product and comparatively list the generic cyclandelate available with the brand-name CYCLOSPASMOL as a reference. The court reasoned that the use of such catalogs amounted to a suggestion to pharmacists that they take advantage of the opportunity to engage in "misconduct". The problem is that the manufacturer-petitioners do not distribute their products or catalogs to retail pharmacies (with a few exceptions). There was clearly no basis for holding these companies liable as contributory trademark infringers, even under the court's own reasoning.

3. The court held that the generic companies had suggested, at least by implication, that the druggist or pharmacist engage in mislabelling to their "economic advantage". This statement is inexplicable. The lower court had found that all but one of the pharmacists who had mislabelled while lawfully substituting had charged the lower generic price for this product. There was thus no economic advantage to the druggist.

4. While conceding that the earlier instances of illegal substitution had been found by Judge Friendly to be insufficient and not widespread, Judge Mansfield nevertheless claims that the generic drug companies should have known that a substantial number of druggists would illegally substitute the generic product in place of CYCLOSPASMOL and that in fact illegal substitution of CYCLOSPASMOL is widespread. This result was accomplished by the court's taking judicial notice of six indictments handed down in New York City *after* the trial had been completed. The six indicted pharmacists were alleged to have illegally substituted generic products in place of CYCLOSPASMOL (as well as other products). The court stated that it was expressing no opinion as to the guilt or innocence of the parties in question. Yet at the same time, the court took

notice of the indictments as supposed proof that illegal substitution was widespread. The argument simply does not follow.

5. Judge Mansfield recognized that the evidence of illegal substitution of generic cyclandelate for CYCLOSPASMOL was scanty. The opinion nonetheless states that "taking into consideration the normal reluctance of any druggist to admit illegal conduct, it was surprising that Ives was able to produce as many such instances as it did." (Pet.App. 81a) The evidence of illegal substitution which was produced had nothing to do with admissions of illegal conduct by pharmacists. Rather, Ives based its evidentiary submission upon extensive shoppings it conducted in which bogus prescriptions were presented to unsuspecting pharmacists in an attempt to uncover illegal conduct. Many of these pharmacists were previously known to Ives to have a tendency to engage in illegal acts of substitution. This evidence does not support Judge Mansfield's conclusion.

We respectfully submit that the trial court's findings were fully supported by the record. We further submit that the reversal of those findings works a serious and unwarranted hardship on both the generic drug industry and the public.

CONCLUSION

For the foregoing reasons, NAPM respectfully requests that the decision of the United States Court of Appeals be reversed.

Respectfully submitted,

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Brief *Amicus Curiae* of the Attorney General of the State of New York

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Brief *Amicus Curiae* of the Attorney General of the State of New York.

Interest of *Amicus Curiae* New York State.

The Attorney General of the State of New York submits this *amicus curiae* brief pursuant to Rule 36(4) of the Rules of this Court, since the holding of the Court of Appeals for the Second Circuit may adversely affect an important legislative policy of the State of New York.

In 1977, New York State joined a nationwide trend when it enacted its "Generic Drug Substitution Act" (L 1977, ch 776), which permits prescribing physicians to authorize pharmacists to substitute therapeutically equivalent generic drugs for their more expensive brand name counterparts.* As stated by Governor Hugh Carey in his memorandum approving this statute, its purpose is "to reduce health care costs without sacrificing quality" (New York State 1977 Legislative Annual, pp 258-9). The importance of this legislative object was recognized by the Court of Appeals for the Second Circuit in affirming denial of an injunction against implementation of the New York law:

> "* * * the local benefit is the potential saving to New York patient-consumers based on the price differentials between brand name drugs and lower-priced generic equivalents, which represents a legitimate interest. See *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,* 425 U.S. 748, 763-64, 96 S. Ct. 1817, 48 L.Ed. 2d 346 (1976)."

Pharmaceutical Society of the State of New York v Lefkowitz, 586 F2d 953, 957 (2d Cir, 1978).

*Prior to 1972, virtually every state had a drug "anti-substitution" law which prevented pharmacists from deviating from the face of a prescription, despite the availability of less expensive generic alternatives (*Drug Product Selection,* Staff Report to the Federal Trade Commission [1979], p 150). In light of heightened Federal regulatory control over drug efficacy (see, 21 USC § 355[d], [e]), the 1970s saw a rapidly accelerating repeal of these laws and their replacement with statutes permitting drug substitution. Forty-eight states, the District of Columbia and Puerto Rico have now enacted such laws (see, Appendix A; see also, "Competition in the Drug Industry: Hearings Before the Subcom. on Oversight & Investigations," House Comm. on Energy & Commerce 13, 91st Cong, 1st Sess. (3/10/81); Warner, "Consumer Protection and Prescription Drugs: The Generic Drug Substitution Laws," 67 Ky. L.J. 384 (1978-9).

This state purpose, embodied in legislation throughout the country, is hindered by the holding of the Court of Appeals for the Second Circuit in the instant case. That Court has held that Ives Laboratories can bar generic pharmaceutical manufacturers and distributors from using the colors of its promoted brand drug, "Cyclospasmol." As found by the District Court in this matter (488 F Supp 394, 399-400 [EDNY, 1980]), this inability by generic manufacturers to use a brand name drug's accustomed color tends to confuse patients as to the content and effect of generic drugs substitutable under New York's "Generic Drug Substitution Act." This confusion increases, without any scientific basis, patient resistance to drug substitution, thus undermining the State policy seeking to promote greater use of approved substitutes to reduce drug costs. Moreover, the resultant increased sale of more expensive drugs means increased costs to the State for Medicaid payments to eligible recipients.

Summary of Argument.

The State of New York has, through its "Generic Drug Substitution Act" (L 1977, ch 776), expressed a clear policy of promoting the substitution of less expensive generic drugs which are therapeutically equivalent to brand name "reference" drugs. The Court of Appeals for the Second Circuit has inhibited this policy by holding that generic drugs cannot be marketed in the same color as their brand name counterparts. Confusion caused by the marketing of equivalent drugs with different colors increases patient resistance to the drug substitution sought to be encouraged in New York State.

Moreover, the Court of Appeals for the Second Circuit erred in basing its determination in part upon judicial notice of indictments alleging illegal drug substitution and mislabelling in New York City. These indictments do not

support that Court's holding, but indicate instead a vigorous and effective State enforcement program to protect the very interests asserted by the respondent, Ives Laboratories, Inc., in this matter.

ARGUMENT.

Preventing the use of generic drugs of the same color to which consumers were accustomed in their prior use of the brand name product interferes with a valid State policy, expressed not only in New York but by the Legislatures of 48 states.

After the trial, the District Court made the following factual findings relevant to the State's interest as described above (488 F Supp 394 [E.D.N.Y. 1980]):

1. Ives offered no proof that the generics involved had a therapeutic effect differing from that of the Ives Laboratories promoted brand, "Cyclospasmol" (*id.* at 396).

2. Under New York law, the pharmacist may properly but need not substitute the particular drug involved (*id.* at 397; see to the same effect, 638 F2d at 541, n 5).

3. Nine of ten pharmacists who used the "Cyclospasmol" name when dispensing a generic told the patients about it and only one charged a higher "brand" price (488 F Supp at 397).

4. The similarity of color is functional in that many elderly patients associate the appearance of their medication with its therapeutic effect, and others commingle drugs in a single container and rely on appearance to follow their doctors' instructions; color is also useful to

doctors and hospital emergency rooms in identifying overdoses of drugs (*id.* at 399-400).

5. There is no reason to suppose that drug color has acquired a secondary meaning, since patients, as distinct from physicians, do not associate "Cyclospasmol" with a particular manufacturer (*id.* at 400), nor was there any evidence that physicians were deceived by color identity.

These findings were supported by the record, as noted by Judge Mulligan, in his dissent in the Court of Appeals (*Ives Laboratories, Inc. v. Darby Drug Co.*, 638 F2d 538, 547 [2d Cir, 1981]). Nonetheless, the majority in the Court of Appeals found a lack of concrete evidence for the District Court's explanation that mislabelling occurs because of confusion rather than as a result of inducement (*id.* p 544).

The State of New York believes that the District Court was correct in holding that any benefit accruing from patient ease in detecting an improper drug substitution is far outweighed by the State's legitimate interest in fostering the use of generic substitutes. As noted by that Court "[t]o require different capsule colors might to some extent deter a wrongdoer but it would also severely inhibit legal substitution which the legislature deems to be in the public interest" (488 F Supp at p 401). The Court of Appeals erred in failing to take this vital public interest into account.

Moreover, the Court went on to take judicial notice of indictments handed down in the New York City area alleging illegal substitution and mislabelling of generic cyclandelate in prescriptions requiring cyclospasmol, and to hold that these indictments are inconsistent with the contention that mislabelling is rare or unintentional. The

fact is that the indictments are simply a mark of the effective Medicaid fraud enforcement program which is carried on in New York.*

New York State has adopted a systematic effort to police implementation of the drug substitution and Medicaid programs. As part of this effort, the State seeks to see that consumers obtain the benefits of the drug substitution law, including knowledge of when substitution occurs and the benefit of any lower price. This effort includes enforcement of the State's ban on misbranding and the requirement that the correct proprietary names of material prescribed be shown on labels (New York Education Law, §6815[2]). The State effort includes both reception of complaints of alleged violations and also sample purchases.

As already noted, the clear State policy of promoting substitution of equivalent generics is undermined by the holding of the Court of Appeals. But beyond that it would be extremely ironic if this Federal intrusion were justified in part by the very success of a State enforcement program designed to protect the interest asserted by Ives in the instant matter.

As a result of the State's effort, indictments have been obtained in numerous cases, some of which were cited by the Court of Appeals, as noted above, in support of its conclusion that a ban on similarity of colors of promoted and generic cyclandelate was necessary to prevent misbranding in violation of section 32 of the Lanham Trade-Mark Act, 15 USC, §1114. The conclusion of the Court of Appeals is based on the assumption that New

*The State's effective cost containment and Medicaid fraud enforcement programs have earned Federal recognition in the form of forgiveness of otherwise applicable Federal funding reductions (see New York Times, 11/8/81, p 6E).

York State's program is ineffective, for which no support in the record is cited.

There is no statutory indication that Congress authorized the Federal courts to intrude and undermine State policy in the manner mandated by the Court of Appeals, especially when, as here, Ives deliberately chose to bypass available State remedies and instead to pursue exclusively its efforts to get the Federal courts to grant it a color monopoly.

Even if a section 32 violation had been properly found, the remedy imposed by the Court of Appeals is excessive and unduly infringes on State interests. Certainly, there are less intrusive alternative remedies available to prevent deception. For example, a requirement of a logo or imprint in a contrasting color, so as to be readily visible even on the small capsule, was never considered by the Court of Appeals.

CONCLUSION.

The decision of the Court of Appeals should be reversed, and that of the District Court reinstated.

Dated: Albany, New York
November 23, 1981

Respectfully submitted,

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APPENDIX "A."

State Statute Citations—Generic Substitution Acts*

1. Alabama Code §34-23-8 (1979)

2. Alaska Stat. §08.80.295 (1976)

3. Arizona Rev. Stat. Ann. §32-1963.01 (1979)

4. Arkansas Stat. Ann. §72-1049 (1976)

5. California (Business and Professions) Code §§ 4047.6 and 4047.7 (1976)

6. Connecticut Gen. Stat. Ann. §§ 20-185a through 20-185f (1976)

7. Colorado Rev. Stat. §12-22-124 (1978)

8. Delaware Code Ann. Tit. 24, §2589 (1979)

9. Florida Stat. Ann. §465.025 (1976)

10. Georgia Code Ann. §§ 79A-408.1 through 79A-408.5 (1978)

11. Hawaii Drug Product Selection Act; Hawaii Rev. Stat. Tit. 19, §§ 328-91 through 328-99 (1979)

12. Idaho Ann. §§ 18-479-446; 17-479-460 in acc. with §37-2702(d), (1979) (see latest supplement)

13. Illinois Rev. Stat. ch 111, § 4033 (1977)

14. Indiana—none

15. Iowa Stat. Ann. §155.37 (1976)

16. Kansas Stat. Ann. §65-1637a (1979)

17. Kentucky Rev. Stat. §217.822 (1978)

18. Louisiana Rev. Stat. Ann. §37-1225 (1979)

19. Maine Rev. Stat. Ann. Tit. 32, §2806 (1979)

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*Year included is the year of passage. Reference is to the most recent volume, supplement, or pocket part.

20. Maryland (Health) Code Ann. §43-273A (1978)

21. Massachusetts Ann. Laws ch 112, §12D (Hichie/Law Co-op) (1976)

22. Michigan M.C.L.A. §333.17755 (1978)

23. Minnesota Stat. Ann. §151.21 (1975)

24. Mississippi Code Ann. §§ 75-29-701 through 75-29-709 (1979)

25. Missouri Drug Product Selection Law Mo. Ann. Stat. §338.056 (1979)

26. Montana Drug Product Selection Act; Mont. Rev. Codes Ann. Tit. 37, ch 7, §§ 501-510 (1977)

27. Nebraska Drug Product Selection; Neb. Rev. Stat. §§ 71-54.01 through 71-54.08 (1977) (found in 1980 Supp.)

28. Nevada Rev. Stat. §§ 639.2581 through 639.2599 (1979)

29. New Hampshire Rev. Stat. Ann. ch 146 §6-b (1973)

30. New Jersey Stat. Ann. §§ 24:6E-6 and 24:6E-7 (1977)

31. New Mexico Stat. Ann. §26-3-3 (1976)

32. New York—Chapter 776, Laws of 1976

33. North Carolina Gen. Stat. §90-76.1—76.6 (see 1980 Supp.) (Article 4—Pharmacy)

34. North Dakota Cent. Code §19-02.1—14.1 (1979)

35. Ohio Rev. Code Ann. §4729.38 (1978)

36. Oklahoma—none

37. Oregon Rev. Stat. §689.515 (1977)

38. Pennsylvania Stat. Ann. Tit. 35, §§ 960.1—960.7 (1976)

39. Rhode Island—Gen. Laws §5-19-38 (1976)

40. South Carolina Drug Product Selection Act of 1978 Code §§ 39-24-10 through 39-24-40

41. South Dakota—Codified Laws Ann. §§ 36-11-46.1 through 36-11-46.4 (1978)

42. Tennessee—Substitution of Equivalent Drug Product Act; Tenn. Code Ann. §39-2201 (1977)

43. Texas [Health] Code Ann. Tit. 4542, §12 (1978)

44. Utah—Generic Drug Substitution Act; Utah Code Ann. §§ 58-17-29 through 58-17-35 (1977)

45. Vermont Stat. Ann. Tit. 18, §4605 (1977)

46. Virginia Code Tit. 32.1, §§ 79-88 (1976)

47. Washington Rev. Code Ann. §§ 69.41.100 through 69.41.180 (1977)

48. West Virginia—Code §30-5-12b (1978)

49. Wisconsin—Stat. Ann. §140.90 (1976)

50. Wyoming—Generic Drug Substitution Act; Wyo. Stat. §§ 33-24-146 through 33-24-151 (1979)

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On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF FOR THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

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BRIEF FOR THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

INTEREST OF AMICUS CURIAE

The Pharmaceutical Manufacturers Association ("PMA") is a voluntary nonprofit association of 149 companies engaged in the discovery, development, manufacture and marketing of prescription drugs, medical devices and diagnostic products. Its member companies have created and introduced, at great expense and scientific effort, most of the prescription drugs on the market today. They differ in this respect from so-called generic drug manufacturers, such as petitioners, who engage in no research and development but concentrate their efforts on the manufacture and sale of generic formulations of drugs developed by others.

At issue in this case is the practice of some generic manufacturers of making their products in the same size, shape and color as the trademarked "pioneer" products of many PMA members. If the Court were generally to uphold the legality of these "look-alikes," consumers would be left with no effective protection against deceit, and the ability of innovative manufacturers to build and

protect a reputation for quality and reliability would be severely impaired, thus distorting competition in the market. PMA therefore files this brief as *amicus curiae* supporting respondent to set forth its views on the broad policy questions implicated by petitioners' claims.[1]

THE ESSENCE OF THE CONTROVERSY

This case challenges the attempts of three manufacturers of generic prescription drugs to bolster their competitive positions by dressing their cyclandelate drug products so as to make them identical in size, shape and color to respondent's original and well-accepted cyclandelate product Cyclospasmol.® The avowed purpose of such imitation (Darby Br. at 11 n.*) is "to equate their products with the market leaders in every way, except for price." This implied representation that "look-alikes" are the same as the originals "in every way" is contrary to fact—certainly as to the source of the product, and in all likelihood as to manufacturing methods, quality control procedures and "inactive" but necessary ingredients that can affect the drug's therapeutic performance. It is deception in the most simple and obvious sense: the consumer does not receive what he is led to believe he is getting.

In every modern case of this kind, including this one, the courts have held that the manufacture and sale of "look-alike" drugs is unlawful. But neither this case nor any of its predecessors has had the purpose or effect of preventing fair and open competition between generic and trademarked prescription drug products. Rather, these cases all have been concerned with consumer deception. The courts have acted to protect the consumer's right to know whether the medication he is receiving from his pharmacist is the trademarked product prescribed, or a generic substitute.

As the evidence in these cases bears out, the method by which prescription drugs are sold makes it inevitable

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[1] Pursuant to the Court's Rule 36.2, the written consents of all parties to this case are being filed with the Clerk herewith.

that "look-alike" drugs will be used by some pharmacists as an instrument of consumer deception. Although all drug manufacturers are required by law to distribute their products to retailers in containers that clearly identify their source, the drugs themselves are rarely dispensed to consumers in their original packages. Instead, pharmacists usually remove the products from the original packages and dispense them in their own containers, affixed to which are labels typed by the pharmacists themselves. Thus, where substitution of generics is permitted, a pharmacist can easily dispense a "look-alike" and label it with the original's trademark, with confidence that the patient will not know the difference. Even worse, a pharmacist can practice deception by using a "look-alike" generic to fill a prescription that specifically requires the trademarked product.

As will be shown below, there is a strong economic incentive for pharmacists to engage in illegal substitution and mislabeling. Pharmacies' profit margins on generic drugs are often higher than on the trademarked original products, even when they sell the generics at prices below those generally charged for the trademarked drugs. And, of course, a pharmacist bent on deception can easily pass off a "look-alike" as the trademarked product at a price that only the well-accepted original could truthfully command.

Although petitioners and their *amicus* supporters have suggested that it is traditional for generic drugs to be manufactured to resemble their brand-name counterparts, the fact is that the problem presented by this case is relatively new. Before 1970, concern that generic drugs might be inferior to brand-name products had led most states to enact "anti-substitution" laws prohibiting pharmacists from dispensing generic substitutes when physicians had prescribed drugs by brand name.[2]

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[2] *See* Note, *Consumer Protection and Generic Drugs: The Generic Drug Substitution Laws*, 67 Ky. L.J. 384, 389-90 (1978-79); Grabowski & Vernon, *Substitution Laws and Innovation in the Pharmaceutical Industry*, 43 Law & Contemp. Prob. 43, 49 (1979).

To the extent generics were marketed in "look-alike" form to facilitate substitution, they were intentional instruments of illegality and fraud.[3] Not until the 1970's did the states begin to replace these anti-substitution laws with statutes that permit or require substitution of generic for trademarked drugs unless expressly prohibited by the physician. It was the enactment of these new substitution laws that first created a large lawful market for generic drugs,[4] and thus made the "look-alike" issue one of widespread concern.

The new state substitution laws, however, are in no way intended to encourage or even condone consumer deception. To the contrary, these laws generally contemplate that patients will be informed of any substitution, and they all also permit physicians to write prescriptions so as to preclude substitution of a generic for the trademarked product. Their purpose is to provide consumers with a choice, not to facilitate fraud.

The "look-alike" manufacturers claim that their products are in all respects medically equivalent to their trademarked original counterparts. But, as we shall show, this is not always so. It is therefore prudent, and surely not irrational, for physicians or patients to insist upon a particular brand whose therapeutic and other relevant characteristics are well known to them. But regardless of this, the right of the consumer to choose, and to be accu-

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[3] When "look-alike" marketing was encountered, "pioneer" manufacturers sought and generally obtained relief under state unfair competition law against "look-alike" imitators of their product sizes, shapes and colors. *See, e.g., Ross-Whitney Corp. v. Smith Kline & French Labs.*, 207 F.2d 190 (9th Cir. 1953); *Smith Kline & French Labs. v. Broder*, 125 U.S.P.Q. 299 (S.D. Tex. 1959); *Smith Kline & French Labs. v. Midwest Chem. Dev. Corp.*, 96 F. Supp. 797 (N.D. Ohio 1951); *Smith Kline & French Labs. v. Heart Pharmaceutical Corp.*, 90 F. Supp. 976 (S.D.N.Y. 1950), which petitioners conveniently all but ignore.

[4] In 1966, for instance, only 6.4% of new prescriptions were written generically. *Drug Product Selection: Staff Report to the Federal Trade Commission* 45 (1979).

rately informed, is at the heart of the competitive system. It is this principle that the Second Circuit in this case, and other courts in similar cases, have sought to preserve.

SUMMARY OF ARGUMENT

I.

This case does not present the "look-alike" issue in a form that would enable the Court fully to resolve it. Every other recent case on this subject has held the "look-alike" practice to be unlawful under Section 43(a) of the Lanham Act, but the Second Circuit in this case relied solely on Section 32 of the Act to reach the same result. Thus, regardless of whether this Court affirms or reverses the judgment below, the Section 43(a) issue would remain unresolved. This case is therefore not a suitable vehicle for settling the "look-alike" issue, and accordingly the writ should be dismissed as improvidently granted.

II.

The practice of manufacturing and marketing generic prescription drugs in the same size, shape and color as the original trademarked products they seek to supplant serves no purpose other than consumer deception.

A. Petitioners' efforts to justify "look-alikes" on health-related grounds will not withstand analysis. Their arguments have been rejected by every court that has considered them (except the district court in this case), as well as by the Food and Drug Administration.

First, petitioners argue that a patient who receives a generic drug that differs in appearance from the trademarked product to which he is accustomed will experience "anxiety" about whether the generic is therapeutically equivalent. But generics may only be substituted for the trademarked drug prescribed if the physician and the patient have agreed to accept such substitution, which should allay any concern about the generic's outward appearance. The "anxiety" feared by petitioners is the

reluctance of some patients—not necessarily unfounded—to accept generic substitutes for their accustomed trademarked products, an "anxiety" petitioners seek to avoid by camouflaging the differences between the two.

Second, petitioners argue that patients sometimes commingle several medications, and rely on the color to differentiate one from another. But even if some patients use this risky method of identifying different drugs, a generic can be as easily distinguished from other medicines when it has its own distinctive color.

Third, petitioners contend that the color of a drug product can assist physicians in determining what drug was taken by an overdose victim. In fact, however, physicians cannot and do not rely on color for this purpose, as unrelated drugs often look alike.

Although the district court purported to find as a "fact" that the medical justifications offered by petitioners for "look-alikes" were valid, this is not really an issue of fact to be decided again and again on the record of each case. There must ultimately be one rule as to whether "look-alike" generic drugs serve any legitimate purpose. The rule should be, as the lower courts have consistently held, that "look-alikes" serve no purpose but consumer deception.

B. Nor is there merit in petitioners' argument that only "look-alike" generics can compete effectively with brand-name products. There are many successful generic drugs on the market that do not imitate the appearance of the original trademarked products they seek to supplant, and generic manufacturers as a class are thriving.

C. For public health reasons, consumers must be able readily to recognize generic substitutes. In too many instances, generics differ from the trademarked originals in important pharmacologic respects. The unlawful substitution and mislabeling made practicable by "look-alike" appearance leads consumers unknowingly to accept products that can in some cases cause serious injury or death.

III.

The practice of marketing "look-alikes" is inconsistent with the consumer-choice and pro-competitive policies of state substitution laws. These laws permit the substitution of generic for prescribed trademarked products only with the consent of the physician and the patient. "Look-alike" drugs enable the pharmacist to deceive the patient, and thus undermine this fundamental right of consumer free choice. Moreover, if petitioners cannot offer products so well suited for deception they will have to find other competitive weapons—presumably, price. Allowing "free riders" on the pioneer manufacturers' reputations is also likely to discourage innovation, and thus impair competition and economic efficiency. Finally, "look-alike" appearance makes it possible for manufacturers of defective drugs to shift liability for the harm caused by their products, thus further distorting competition.

IV.

The court of appeals correctly held that petitioners were guilty of contributory trademark infringement under Section 32 of the Lanham Act.

A. Petitioners claim that they should not be held liable for the infringements committed by pharmacists, because they neither intended nor had reason to anticipate that their products would be used in that fashion. The evidence in this record, however, as well as the evidence in numerous similar cases, establishes that mislabeling and illegal substitution are widespread and pervasive. Furthermore, as petitioners also are aware, there is often a strong economic incentive for pharmacists to engage in these practices, because of the higher profits available to them on sales of generics. Thus, petitioners had every reason to anticipate infringement.

B. The decision below is fully consistent with this Court's decisions in *Sears* and *Compco*. Those cases merely held that state unfair competition laws could not be used to prevent copying of the configuration of

products that were not protected by patents. In this case, we are concerned with federal, not state, law; the issue is trademark infringement and deception, not product simulation as such; and the practice involved is copying of trade dress, not the configuration of the product itself.

ARGUMENT

I. BECAUSE THIS CASE IS NOT A SUITABLE VEHICLE FOR RESOLVING THE "LOOK-ALIKE" CONTROVERSY, THE COURT SHOULD DISMISS THE WRIT AS IMPROVIDENTLY GRANTED.

Although the lawfulness of "look-alike" generic drugs is clearly an important issue, this case does not present that issue in a form that would enable the Court fully to resolve it. Accordingly, PMA respectfully suggests that the Court proceed no further with this case, but instead dismiss the writ of certiorari as improvidently granted.

In every modern case in which the manufacture and sale of "look-alike" drugs have been challenged, including this one, the plaintiff's principal claim has been that the practice constitutes false designation of origin and false representation in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and unfair competition under state law. In some cases, as here, plaintiffs have also contended that "look-alike" marketing constitutes contributory trademark infringement under Section 32 of the Act, 15 U.S.C. § 1114. In all cases prior to the present one, however, the courts have upheld the plaintiffs' claims under Section 43(a) or equivalent state law principles. In this case, for the first time, the court pretermitted the Section 43(a) issue, and relied entirely on Section 32 to grant relief.

Because the Second Circuit's decision was so limited in scope, this case is not a suitable vehicle for this Court definitively to settle the lawfulness of "look-alike" drugs. Respondent's Section 43(a) claims are still unresolved and will remain so regardless of this Court's ruling on

Section 32. Yet, as the United States notes in its *amicus* brief (at 14-15), "it is that provision, rather than Section 32, which is at the heart of the present controversy." A decision by this Court affirming the Second Circuit will not necessarily control future cases, which, because of differing facts, may turn primarily or wholly on Section 43(a). A decision reversing the Second Circuit, on the other hand, would require a remand for consideration of the Section 43(a) issue, on which the court of appeals has yet to pass [5] and which has not been fully briefed by any party.

We therefore suggest that certiorari was improvidently granted, and that the writ should be dismissed. If the Court reaches the merits of this case, however, for the reasons that follow, it should affirm the decision below.

II. IMITATION OF THE SIZE, SHAPE AND COLOR OF A PRESCRIPTION DRUG PRODUCT SERVES NO PURPOSE BUT DECEPTION OF PATIENTS.

Petitioners and their *amicus* supporters would have the Court believe that original trademarked drugs and their generic imitations are one and the same, in all respects fungible and interchangeable, and that it is a matter of indifference to patients whether they are sold one or the other. This is not so. Generic drugs, while usually containing the same active ingredients as their brand-name counterparts, are made by different manufacturers (often having different reputations for reliability and integrity), are manufactured by different methods using different quality control procedures, and contain different "inactive" but pharmaceutically necessary ingredients. Some generic products, in fact, have been found to have important differences in their pharmacologic effects on patients. See pp. 17-20 *infra*. But

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[5] "We do not ordinarily address for the first time in this Court an issue which the Court of Appeals has not addressed * * *." *J. Truett Payne Co. v. Chrysler Motors Corp.*, 101 S. Ct. 1923, 1930 (1981).

even where no such differences have been directly demonstrated, many physicians and consumers insist upon the trademarked original product, and are unwilling to take chances with generic imitations.[6]

Pharmacists often, however, make a larger profit on generic drugs. See p. 26 *infra*. Thus, even when prescriptions specifically require trademarked products, there is an economic incentive to substitute generic products. The fact that generic cyclandelate is sold in capsules identical in size, shape and color to Cyclospasmol ® makes it easy—and undoubtedly tempting—for a pharmacist to fill a prescription that calls specifically for Cyclospasmol ® with a "look-alike," without fear of detection. All he need do is to type Cyclospasmol ® on the label.

Even if a pharmacist is unwilling to engage in such blatant misconduct, moreover, few consumers would be alerted to a substitution—legal or illegal—by a label that says "generic Cyclospasmol," much less "Cyclospasmol (gen)" or the like:

> Whether adding the letters "Gen" or the word "generic" actually tells the consumer that he or she is being switched * * * is questionable—absent explicit information from the pharmacist. Consumers are unlikely to learn of the change in medication from what is probably, for them, an obscure word or phrase.

Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, Inc., 211 U.S.P.Q. 1163, 1181 (D.N.J. 1980). If a patient has been taking a specific trademarked product, has a prescription naming that product, and receives a

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[6] The Food and Drug Administration has acknowledged that among prescription drug consumers, especially the elderly, "doubts * * * may exist regarding the safety, effectiveness, and economic advantage" of generics. 45 Fed. Reg. 72582 (Oct. 31, 1980). Consumer preference for a particular brand is especially common in the case of drugs that are used for extended periods, such as Cyclospasmol.® Patients who have had good results with a particular product are frequently unwilling to experiment with generic substitutes.

pharmacist-prepared vial of capsules that look identical to that product, he will naturally assume that he has received that product.

This is why so many cases under Section 43(a) of the Lanham Act have held that the size, shape and color of the drugs involved have a "secondary meaning" identifying their source. Those courts have recognized that consumers rely on appearance to identify trademarked prescription drug products to which they are accustomed.[7]

The evidence in this case, involving 34 separate instances of trademark infringement,[8] illustrates how "look-alikes" facilitate consumer deception. Petitioners' disclaimers of intent to deceive, and purported justifications for marketing "look-alikes," cannot withstand examination.

A. The Purported Medical Justifications for "Look-Alikes" Are Invalid.

Petitioners seek to justify "look-alike" drugs on a variety of health-related grounds. These same arguments have been rejected by every court that has considered

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[7] *SK&F, Co. v. Premo Pharmaceutical Labs., Inc.*, 625 F.2d 1055, 1064 (3d Cir. 1980); *A.H. Robins Co. v. Medicine Chest Corp.*, 206 U.S.P.Q. 1015, 1020 (E.D. Mo. 1980) (in which petitioner Inwood was a defendant); *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1178 (in which petitioner Premo was a defendant); *Smith Kline & French Labs. v. Midwest Chem. Dev. Corp.*, 96 F. Supp. 797, 798-99 (N.D. Ohio 1951); *Smith Kline & French Labs. v. Heart Pharmaceutical Corp.*, 90 F. Supp. 976, 977 (S.D.N.Y. 1950).

[8] In 15 cases, pharmacists used generic cyclandelate to fill prescriptions specifically requiring Cyclospasmol.® Pet. App. 52a & n.17. (Twelve of these were labeled with Ives' trademark alone, *id.*; a 13th was labeled "Cyclospasmol 400 mg Bolar Equivalent," Pl. Ex. 98, R. 247-49.) Ten "substitution permissible" prescriptions (29% of the relevant shoppings) were filled with generic cyclandelate mislabeled as Cyclospasmol.® Pl. Exs. 82A, E, S, T, BB, DDD, R. 392-93; 82 HHH, OOO, SSS, TTT, R. 85, 377. Finally, nine vials of generic cyclandelate, out of a total of 17 that were examined while in the possession of patients, were mislabeled as Cyclospasmol.® Pl. Exs. 28-30, R. 109a, 111a-12a, 114a; 33-38, R. 66b, 70b, 78b, 82b.

them (except the district court in this case),[9] as well as by the Food and Drug Administration.[10] They deserve the same fate here.

First, petitioners argue that if a patient who is accustomed to a trademarked product is given a generic substitute having a different appearance, he will be apprehensive about the equivalence of the generic, and that this "anxiety" may impair both the acceptability and even the effectiveness of the drug.[11] In effect, this is an argument that deception is good for the patient, that it is better for him *not* to know that the drug he is receiving is not in all respects identical to the trademarked product prescribed.

As the United States points out in its *amicus* brief, this is the "highly paternalistic approach" repudiated by this Court in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976). In addition, it flies in the face of state substitution laws, which generally contemplate that the patient be informed when a generic is substituted for a trademarked product prescribed by his physician. See pp. 20-21 *infra*. FDA, too, "recognizes the need for consumers to be in-

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[9] *See SK&F v. Premo, supra*, 625 F.2d at 1060-61; *Biocraft Labs., Inc. v. Merck & Co.*, No. 77-693 (D.N.J. Oct. 2, 1980), slip op. at 12; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171-72; *Hoffmann-La Roche, Inc. v. Premo Pharmaceutical Labs., Inc.*, 210 U.S.P.Q. 374, 385 (D.N.J. 1980).

[10] FDA has denied a petition by *amicus* the National Association of Pharmaceutical Manufacturers ("NAPM"), based on the same arguments advanced here, to impose a general requirement that all formulations of a prescription drug—generic and trademarked—be manufactured in the same size, shape and color. FDA's letter denying the NAPM petition is reproduced at pp. 1a-2a *infra*.

[11] There is no suggestion in this record that the colors selected by Ives for its Cyclospasmol ® capsules were chosen on any therapeutic or psychological basis. They were selected arbitrarily, solely to give these products a distinctive trade dress. Thus, the argument of *amicus* NAPM (Br. at 4, 5, 8) that the colors of some drugs are chosen for their psychological effects has no bearing whatsoever on this case.

formed when drug substitution occurs in order to prevent them from receiving another product without their knowledge." 45 Fed. Reg. 72582, 72596 (Oct. 31, 1980).[12]

A properly informed patient who accepts a generic substitute is unlikely to feel any "anxiety" about differences in appearance between the generic and the brand-name drug; he will understand that they are made by different manufacturers. *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171. If instead he insists on receiving "the real thing," the trademarked product he has long known and used, that is his right, whether petitioners want him to exercise that choice or not. "[T]he public is entitled to get what it chooses * * *." *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 78 (1934).[13]

If an informed patient experiences any "anxiety" about a generic with a different appearance, it is not because he is apprehensive about the appearance of the drug *per se*, but because he prefers the security of the brand name's history and reputation. Thus, the lower courts[14] have rejected the contention that the avoidance of patient anxiety justifies "look-alike" marketing.[15]

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[12] Petitioners suggest that elderly patients may not be capable of understanding or making the necessary choices. But the elderly no less than any other consumers are entitled to full disclosure when a generic has been substituted. If a patient, young or old, has some mental impairment, the physician will know how to deal with the problem.

[13] *Cf. General Motors Corp.*, 93 F.T.C. 860 (1979) (consent order to cease and desist, on allegations that Chevrolet engines were substituted in Buick, Oldsmobile and Pontiac cars without informing purchaser).

[14] *SK&F v. Premo, supra*, 625 F.2d at 1061; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171; *Hoffmann-La Roche v. Premo, supra*, 210 U.S.P.Q. at 385.

[15] Although petitioners claim that some hospitals demand generics in "look-alike" form, the record in this case contains next to no evidence that this is so. But insofar as some hospitals might insist on "look-alikes," they too can only be attempting to stifle a legitimate form of consumer "anxiety"—the lack of confidence that

Second, petitioners contend that patients who are taking more than one drug may sometimes commingle them and rely on appearance to differentiate one from another. But even if some patients do use this risky method to distinguish their medicines, the differentiation can as readily be made with non-"look-alike" drugs, as long as they differ from others the patient is taking. *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1171-72.[16]

Third, petitioners assert that "look-alike" appearance assists emergency room physicians in identifying the drugs taken by overdose victims. But so many unrelated drugs look so similar that doctors cannot and would not rely on color and form alone to identify the drug taken. *E.g.*, *SK&F v. Premo, supra*, 625 F.2d at 1060.

Petitioners contend that the issue whether any legitimate purpose is served by making their generic cyclandelate products look like Ives' Cyclospasmol® is an issue of fact, and that the district court's rulings on that issue in their favor are not "clearly erroneous" and must therefore be upheld. We submit, however, that this is not an issue of fact, to be decided

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some patients have in generic substitutes of unfamiliar or dubious provenance. By dispensing "look-alike" drugs, these hospitals hope to avoid the questions that might be asked, or the objections that might be raised, by patients who are alerted to a substitution. Deception on the part of hospitals, even if benignly motivated, is no more acceptable than deception by retail pharmacies. Hospitalized patients should not be denied the protection provided by the Lanham Act against deception, as the United States in its *amicus* brief (at 32) seemingly would do.

[16] If a physician is concerned that renewal prescriptions will be filled with generics of different colors and that his patient is not alert enough to remember the color of the current prescription, he can prescribe a particular generic by name. Some generic manufacturers—including prominent members of petitioners' *amicus* supporter NAPM—directly advertise to physicians, urging that "[d]octors should specify," *e.g.*, "Biocraft * * * high quality generic drugs." 305 N. Engl. J. Med. xxxvi (Dec. 3, 1981).

anew—and perhaps inconsistently—in each case.[17] The same issue arises in every "look-alike" case, and the arguments presented do not vary according to the particular drug at issue.[18] It would be irrational to hold that the result in each case depends upon how a particular fact-finder happens to evaluate the particular record made on these matters of general applicability. There must ultimately be one rule as to whether "look-alike" generic drugs serve any legitimate purpose.[19] In framing that rule, the Court must be free to examine not only this record but other cases, as well as other sources of information, to reach a judgment on the issue as a matter of law. Every court to pass upon the question, except the district court in this case, has held that "look-alike" marketing serves no legitimate purpose. This Court can and should reach the same conclusion.

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[17] The district court in this case held that "look-alike" appearance was "functional"—that it was justified by purposes other than deception. "Functionality," however, is not a fact but a legal characterization, to which the "clearly erroneous" standard does not apply. This Court held in *United States v. Singer Mfg. Co.*, 374 U.S. 174, 193 (1963), that what acts constitute "conspiracy" under the Sherman Act is a matter of law; the district court's "finding" of no conspiracy was overturned because, on the facts as found, this Court held that a conspiracy existed. Here, even if the district court's conclusions about patient "anxiety," commingling of drugs and emergency room identification are deemed to be factual findings, under the Lanham Act these "facts" are insufficient as a matter of law to justify "look-alike" marketing, under the "functionality" rubric or any other. The policy of the Lanham Act against consumer deception outweighs any of these supposed advantages.

[18] The same witnesses testify in these cases for the "look-alike" manufacturers. Dr. Jerry Bloom, for example, testified both in this case and in *Boehringer v. Pharmadyne, supra*.

[19] A different issue might be presented if the color of a medication were chosen because of some unique psychological meaning, or because it was the natural color of the main ingredient—*e.g.*, brown for chocolate or white for milk. But that is not the situation here.

B. Generic Drugs Can Compete Successfully in Non-"Look-Alike" Form.

Petitioners' claim that only "look-alike" drugs can compete effectively with trademarked originals is equally without merit. In fact, as found in several litigated cases, many generics that are manufactured in distinctive form do compete successfully.[20]

Any competitive advantage for "look-alikes," moreover, could only result from the deception of patients. Identity of appearance facilitates sales of generic drugs only to consumers who want the original trademarked product or one identical in all respects, and who are deceived by the appearance of the generic. As the Third Circuit acidly observed, "[p]robably [the "look-alike" manufacturer] could compete better still if it could appropriate the same trade name." *SK&F v. Premo, supra*, 625 F.2d at 1067.[21]

Contrary to the impression left by petitioners, generic manufacturers are no mere upstarts struggling to survive and likely to perish without special privileges. In 1978, sales of generics, at manufacturers' prices, amounted to $1.4 billion or 20 percent of the prescription drug market. By 1985, generic sales are expected to triple.[22] Petitioners

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[20] *See SK&F v. Premo, supra*, 625 F.2d at 1060 n.3, 1064; *Biocraft v. Merck, supra*, slip op. at 12; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1173. The record in *SK&F v. Premo*, Appendix at 183-85, shows that SK&F itself makes 16 generic products in non-"look-alike" form and that, despite a relative lack of promotion, these products compete successfully.

[21] The Generic Pharmaceutical Manufacturers Association, as *amicus curiae*, claims (Br. at 10-11, 26-27) that "look-alike" marketing is competitively necessary because generic manufacturers do not promote their products to physicians and pharmacists as extensively as brand-name manufacturers do. If petitioners find themselves at a disadvantage because they do not sufficiently promote their products, their recourse is to promote more vigorously or find some competitively effective alternative, not to deceive patients.

[22] SRI International, *A U.S. Generics Breakthrough?* 19 (1980).

themselves are among the leaders in generic sales.[23] They need no special dispensation from unfair competition laws to compete successfully.

C. "Look-Alike" Generic Drug Products May Endanger Public Health.

The consumer deception promoted by "look-alikes" can affect more than matters of consumer choice and economic interest. Previous cases have established that generic drugs do not always meet the standards of the trademarked products they imitate.[24] In *SK&F v. Premo*, *supra*, petitioner Premo's "look-alike" version of Dyazide ® released so much more active ingredient into the bloodstream that a toxic accumulation of potassium could result. 625 F.2d at 1061 & n.4.[25]

In *United States v. Premo Pharmaceutical Laboratories, Inc.*, 511 F. Supp. 958, 994-99 (D.N.J. 1981), the district court found similar potentially serious bioavailability differences in Premo's generic versions of five other drugs:

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[23] 184 Am. Druggist 3, 52-70 (1981). Petitioner Rugby, for example, leads all other companies in supplying hydrochlorothiazide for prescriptions that permit substitution. *Id.* at 60.

[24] A "look-alike" may not even contain precisely the same active ingredients as the copied product. *Hoechst AG v. Generix Drug Corp.*, No. 80-6251-Civ.-Jag. (S.D. Fla.), *consent judgment entered*, July 30, 1980; *Eli Lilly & Co. v. Rugby Labs., Inc.*, No. 77 Civ. 27 (E.D.N.Y.), *dismissed pursuant to settlement*, Jan. 16, 1978; *cf. Pennwalt Corp. v. Zenith Labs., Inc.*, 472 F. Supp. 413 (E.D. Mich. 1979), *appeal dismissed*, 615 F.2d 1362 (6th Cir. 1980) (different amount).

[25] Generic products do not contain the same inactive ingredients as the products they imitate, nor are they made by the same processes or subject to the same quality control procedures. This may cause differences in "bioavailability"—the rate at which active ingredients are released into the body—which in turn may mean differences in therapeutic effect. *See United States v. Premo Pharmaceutical Labs., Inc.*, 511 F. Supp. 958, 962-65 (D.N.J. 1981).

Drug [26]	Condition Treated	Potential Adverse Consequences of Varying Bioavailability
trifluoperazine	psychosis	involuntary movements causing permanent injury
allopurinol	gout	urinary failure
doxylamine succinate	nausea due to pregnancy	dizziness, headaches, drowsiness
hydroxyzine pamoate/ hydroxyzine hydrochloride	emotional distress, psychomotor agitation	drowsiness, tremors, convulsive episodes
chlorthalidone	hypertension and edema	cardiac toxicity, leading to death

In *Pharmadyne Laboratories, Inc. v. Kennedy*, 596 F.2d 568 (3d Cir. 1979), the court relied on evidence that Pharmadyne's generic furosemide, as formulated, was "'very likely * * * ineffective'" (at 572 n.8); this, FDA told the court, "could result in serious complications or even death." [27]

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[26] Another inequivalent Premo drug is insulase, used to reduce blood sugar in diabetes patients. The record in *Premo Pharmaceutical Labs., Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980), Appendix at 100, contains evidence that Premo's form of that drug simply did not work.

[27] *Pharmadyne* Appendix at 540a. In a press release issued March 30, 1979, FDA warned of the grave harm that generic furosemides then marketed could cause, and reported four serious incidents. An Ohio pharmacist has been indicted for manslaughter for illegally—and fatally—substituting generic furosemide on a prescription specifying Lasix,® the original brand of the drug. *Ohio v. Cochran*, Cr. No. 81-09-1085 (C.P. Summit County), *indictment returned*, Sept. 11, 1981.

The scientific literature also is replete with evidence that many generics differ in bioavailability from the trademarked products they imitate and that these differences often affect safety or effectiveness. *E.g.*, Office of Technology Assessment, U.S. Congress, *Drug Bioequivalence* 11-14 (1974); D. Chodos & A. DiSanto, *Basics of Bioavailability* (Upjohn Co., 1974); Rubinstein & Eastwood, *The Effect of Lubricant Type and Concentration on the Bioavailability of Furosemide from 40 Mg. Tablets*, 30 J. Pharm. & Pharmacol. 12 (Supp. 1978); DeSante *et al.*, *Generic Propoxyphene:*

Regulation by FDA cannot be relied upon to keep inequivalent generics from the market. All too often, generic products are marketed with no advance FDA review and approval whatsoever, despite the agency's insistence that in most instances to do so is unlawful. *See Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980).[28] The "look-alike" cyclandelate products of petitioners in this very case were placed on the market without any prior FDA review; their legal status under the Federal Food, Drug, and Cosmetic Act is at best unclear.[29]

Need for Clinical Bioavailability Evaluation, 66 J. Pharm. Sci. 1713 (1977); Kramer *et al.*, *Digoxin Bioavailability: Evaluation of a Generic Tablet and Proposed FDA Guidelines*, 66 J. Pharm. Sci. 1720 (1977); Azarnoff & Huffman, *Therapeutic Implications of Bioavailability*, 16 Ann. Rev. Pharm. & Tox. 53 (1976).

[28] *But see United States v. Generix Drug Corp.*, 654 F.2d 1114 (5th Cir. 1981), *petition for cert. filed*, No. 81-1222 (Dec. 30, 1981). Under the Fifth Circuit's ruling, generic drugs can be marketed solely on the *ex parte* determinations of their manufacturers that FDA pre-market review is legally unnecessary and that, as formulated, the unreviewed generic products are in fact safe and effective.

Whatever the legal requirement, moreover, FDA can only proceed by after-the-fact identification and seizure of unsafe or ineffective products where no pre-market approval was sought. And present law not only fails to require, but expressly forbids drug manufacturers to label or advertise their products as approved by FDA. Federal Food, Drug, and Cosmetic Act, § 301(l), as amended, 21 U.S.C. § 331(l). Pharmacists may thus be unaware that the generics they dispense have no FDA approval, and if the unapproved generic is a "look-alike," neither the patient nor the physician will be alerted to the possibility that an unapproved product has been substituted.

[29] *See* Pet. App. 15a. For unapproved generic versions of products—like Cyclospasmol ®—reviewed and approved for safety prior to 1962, but whose effectiveness is still under review pursuant to the Drug Amendments of 1962 (76 Stat. 780), FDA declines to enforce the pre-market approval requirements of the Food, Drug, and Cosmetic Act (§ 505, as amended, 21 U.S.C. § 355) pending completition of the effectiveness review. *See* 40 Fed. Reg. 26142, 26149 (June 20, 1975); FDA Compliance Policy Guide 7132c.08, at 3-4 (Oct. 6, 1976).

Moreover, even FDA approval for marketing does not ensure therapeutic equivalence. "Many" generics that have received the requisite FDA pre-market review and approval are not considered by the agency to be therapeutically equivalent to the pioneer product (or to each other), because of unresolved actual or potential bioavailability problems. 45 Fed. Reg. 72582, 72590-91 (Oct. 31, 1980). Thus, many physicians and consumers understandably insist upon established original products.[30]

III. "LOOK-ALIKE" MARKETING FRUSTRATES THE CONSUMER-CHOICE AND PRO-COMPETITIVE POLICIES OF STATE SUBSTITUTION LAWS.

Although almost all states now permit generic substitution, no state condones—much less encourages—deception of consumers. To the contrary, state laws generally require that patients be informed of any substitution, and,

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[30] It is perfectly reasonable for physicians or consumers to insist on the trademarked products to which they are accustomed even when the state in which they live has judged generic formulations to be therapeutically equivalent. In many instances, other states will have reached the opposite conclusion. Some states, for example, compile "negative formularies," which list generic drugs that may not be equivalent to the brand-name products and that, therefore, the pharmacist may not substitute. Drugs on the negative formularies of some states are not on others. In Arkansas, diphenylhydantoin is on the negative formulary; in Iowa, it is not. Iowa forbids substitution of methaqualone; Missouri allows it, provided the generic is made by a particular company. *See* Arkansas Nonequivalent Drug Product List (n.d.); Iowa Nonequivalent Drug List (Oct. 1981); Missouri Newly Revised Generic Drug Negative Formulary (Oct. 15, 1980).

Other states have "positive formularies"—lists of generic drugs that may be substituted for prescribed trademarked products. Many professionals do not believe that all of the drugs listed on such formularies are as good as the trademarked products. Almost 40% of Wisconsin physicians surveyed do not consider all formulary drugs therapeutically equivalent to the imitated drugs; 35% were undecided; and only about 25% were persuaded that all formulary drugs were equivalent. 48 Wisc. Pharm. 134, 135 (April 1979). If many physicians do not fully trust generics, patients are also entitled to their doubts.

either explicitly or implicitly, give patients the right to refuse the substitute.

The New York statute in this case directs a physician writing a "substitution permissible" prescription that names a trademarked product to inform his patient that a generic drug will be substituted. The patient, if he wishes, can insist on a prescription requiring the trademarked product. *Pharmaceutical Society of the State of New York v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978). The pharmacist is additionally required "to identify the manufacturer of the generic drug substitute for the consumer." *Id.* at 958 n.6.[31]

Freedom of choice is thus a fundamental goal of state substitution laws. "Look-alike" marketing, "instead of advancing that goal, may thwart it." *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, Inc.*, 211 U.S.P.Q. 1163, 1173 (D.N.J. 1980).

Insofar as the states aim to reduce drug costs, the decision of the Second Circuit here is consistent with that purpose. *First*, if generic manufacturers and distributors can no longer market products on the basis of their capacity to deceive, they will have to compete more vigorously as to price.[32] *Second*, "look-alike" manufacturers essentially seek a "free ride" on the efforts and reputation of the brand-name manufacturers who created the market in which they compete. "Look-alikes" deceptively divert the legitimate sales of the brand-name innovators to their lesser-known competitors. Consumers believe they are purchasing one product, when in fact they are pur-

[31] Other states similarly protect the patient's right to refuse a generic product. *See, e.g.*, N.J. Stat. Ann. 24:6E-7 *et seq.* (West Supp. 1981-82). The FTC's Model Drug Product Selection Act, § 2(d), also makes this right explicit. *Drug Product Selection: Staff Report to the Federal Trade Commission* 279 (1979).

[32] Petitioners Darby *et al.* suggest (Br. at 11 n.*) that prices are higher in markets characterized by product "differentiation." This confuses the "differentiation" familiar in economic theory—promotion of products as having distinctively desirable attributes—with "differentiation" of trade dress aimed at preventing deception.

chasing another.[33] This diversion of sales by deception not only constitutes classic "unfair competition," [34] but reduces the economic incentive for discovery and development by innovative manufacturers, in an industry where such incentives may already be insufficient. *See Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 222 (1980).[35] Protection against "free riders" promotes innovation and thus helps, not hinders, competition and economic efficiency. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483 (1974).[36]

Finally, "look-alike" marketing allows companies making defective products to shift liability to innocent trademarked competitors, thus shifting part of their costs and artificially enhancing their competitive positions. As the Third Circuit noted in *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1066 (1980), the "striking similarity" between the products would make it unlikely that the brand-name manufacturer, if sued by an injured consumer of "look-alikes," could escape.[37]

The policies of state substitution laws thus parallel that of the Lanham Act: consumers should not be de-

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[33] Petitioners are plainly wrong in arguing that, when substitution is permissible, mislabeling cannot deprive the brand-name manufacturer of sales. Even in cases where substitution is legal, a patient may prefer the trademarked product. Mislabeling deprives him of the opportunity to make that choice.

[34] *E.g., FTC v. Algoma Lumber Co.*, 291 U.S. 67, 81 (1934); *Pep Boys—Manny, Moe & Jack, Inc. v. FTC*, 122 F.2d 158 (3d Cir. 1941).

[35] The effective patent life of innovative drug products is already diminished substantially by the length of the regulatory approval process. *See Hearings on S. 255 Before the Senate Comm. on the Judiciary*, 97th Cong., 1st Sess. (1981).

[36] *Cf.* Posner, *The Rule of Reason and the Economic Approach: Reflections on the* Sylvania *Decision*, 45 U. Chi. L. Rev. 1, 6 (1977).

[37] An affidavit filed in *Biocraft Labs., Inc. v. Merck & Co.*, No 77-693 (D.N.J.), describes a product liability suit in which only a fortuitous handwritten notation by the pharmacist disclosed that a "look-alike" drug had been substituted for the defendant's product. Affidavit of Ronald S. Henshall (Jan. 6, 1981).

ceived. The decision below reinforces that policy, and should be affirmed.

IV. PETITIONERS ARE GUILITY OF CONTRIBUTORY TRADEMARK INFRINGEMENT.

A. The Use of "Look-Alike" Drugs As An Instrument of Infringement Is So Widespread That Petitioners Must Have Anticipated That Their Products Would Be So Used.

Petitioners deny that they either intended or anticipated that their "look-alike" drugs would be used as an instrument of trademark infringement, so as to make them liable as contributory infringers. The evidence in this record, however, particularly when read in light of comparable evidence adduced in every other contested "look-alike" case—including cases to which petitioners here were parties—demonstrates that mislabeling and illegal substitution of generic drugs for trademarked products is pervasive. The court below thus was clearly correct in concluding that petitioners must have anticipated that their products would be used in this way.

1. As noted above, respondent proved a total of 34 separate instances of infringement.[38] Given the difficulty

[38] Petitioners suggest that labeling generic cyclandelate as "Cyclospasmol 400 mg. (Rugby)," "Cyclospasmol Gen. (Spencer Mead)" or "Hylan: Cyclospasmol" does not constitute trademark infringement. We submit that these uses of the trademark do constitute infringement, as they clearly would confuse and tend to mislead the ordinary drug purchaser. *See Ross-Whitney Corp. v. Smith Kline & French Labs.*, 207 F.2d 190, 197 (9th Cir. 1953); *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs., Inc.*, 211 U.S.P.Q. 1163, 1181 (D.N.J. 1980). They give every appearance of an effort by the pharmacist to disguise the fact that a generic substitute for Cyclospasmol® is being dispensed, by using a misleading label. Pharmacists may not engage in a comparative use of respondent's mark that would "create a reasonable likelihood that purchasers will be confused as to the source, identity, or sponsorship" of petitioners' products. *Smith v. Chanel, Inc.*, 402 F.2d 562, 563 (9th Cir. 1968). And in any event, in three cases the pharmacists simply labeled the generic product as "Cyclospasmol." *See* Pl. Exs. 82T, R. 392-93; 82DDD, R. 393; 82HHH, R. 85, 377.

of obtaining evidence of this kind, as the court of appeals observed (Pet. App. 81a), this number of proven violations is substantial.[39]

2. The evidence of record in other cases further demonstrates that infringement via mislabeling and illegal substitution of generics is widespread.

—In *SK&F v. Premo*, *supra*, test shoppings for Dyazide ® in three cities showed an unlawful substitution rate of four percent. Surveys in other cities showed mislabeling of generic substitutes for Darvon ® in 15 percent of the cases, and for Librium ® in 23 percent.[40]

—In *A.H. Robins v. Medicine Chest*, *supra*, in which petitioner Inwood was a defendant, the court found that on "numerous occasions" the defendant pharmacies had misused plaintiff's trademark Dimetapp.® 206 U.S.P.Q. at 1018.[41]

—In *Boehringer v. Pharmadyne*, *supra*, in which petitioner Premo was a defendant, more than 25 percent of the generics dispensed (six out of 22) were labeled solely with plaintiff's trademark Persantine.® In at least eight additional instances, a misleading label was used. 211 U.S.P.Q. at 1181.[42]

—In *Hoffmann-La Roche v. Premo*, *supra*, out of 65 pharmacies suspected of mislabeling generic products as Librax,® 43 percent (28 out of 65) either mislabeled or

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[39] *Cf. David Sherman Corp. v. Heublein, Inc.*, 340 F.2d 377, 380-81 (8th Cir. 1965).

[40] *SK&F* Appendix at 130-31. *See* 625 F.2d at 1059. The study of Librium ® marketing also revealed an illegal substitution rate of 4%. The court of appeals found these surveys persuasive. *See id.*

[41] The plaintiff's evidence showed that, during a two-year period, two pharmacies in Missouri had received no prescriptions whatsoever calling for generic formulations of Dimetapp,® but that each pharmacy had dispensed at least 1,700 generic tablets, Tr. 422, all illegally. *See* 206 U.S.P.Q. at 1019.

[42] A witness in the case who had been involved in ten or eleven test shopping surveys for various drugs testified that the rate of illegal substitution was 10%. Tr. 607-08.

failed to write any indication of the manufacturer. 210 U.S.P.Q. at 380.

—In *Biocraft v. Merck, supra*, 73.9 percent of the generics substituted in a Florida survey were mislabeled with the plaintiff's trademark Elavil.® Slip op. at 24.[43]

3. The records of other cases still pending, or in which judgment was entered by consent, confirm the prevalence of unlawful substitution and mislabeling.

—In *American Home Products Corp. v. Premo Pharmaceutical Laboratories, Inc.*, Civil No. 81-575 (D.N.J.) (pending), the generic was mislabeled with plaintiff's trademark Equagesic® in 62 percent of the substitutions (16 out of 26). Half of the mislabeled prescriptions bore only the word "Equagesic"; the other half carried such terms as "Equagesic (Shein)," "Equagesic Arb (SM)" and "Equagesic Generic."[44]

—In *Merck & Co. v. Barr Laboratories, Inc.*, Civil No. 80-3791 (D.N.J.), *consent judgment entered*, March 23, 1981, 30 out of 55 substitutions involved mislabeling with plaintiff's trademark Elavil.® Fifteen prescriptions were labeled simply "Elavil" or "Elavil" plus the generic name (amitriptyline), and 15 others bore such labels as "Elavil 25mg. gEq URL," "Elavil/g-25 mg." and "Elavil 25 mg G."

—*Ives Laboratories, Inc. v. Bioline Laboratories*, Civil No. 81-914 (D.N.J.) (pending), concerns cyclandelate, the same drug at issue in this Court. An affidavit filed in that case identifies 40 percent of the substitutions (10 out of 25) as mislabeled. Sixteen percent (four out of 25) were labeled simply "Cyclospasmol" and the other

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[43] In *Smith Kline & French v. Heart Pharmaceutical, supra*, 90 F. Supp. at 977-78, there were 19 examples of passing off. In *Merrell-National Labs., Inc. v. Zenith Labs., Inc.*, 194 U.S.P.Q. 157, 158 (D.N.J. 1977), *denial of redetermination aff'd*, 579 F.2d 786 (3d Cir. 1978), there were nine instances. In *Smith Kline & French v. Broder, supra*, 125 U.S.P.Q. at 302, unlawful substitution took place "in many instances."

[44] Affidavit of Ferdinand Bovoso (Feb. 10, 1981).

24 percent (six out of 25) bore labels such as "Cyclospasmol 200 mg. Generic" and "Cyclospasmol-Gen 200 mg." [45]

Unlawful substitution and mislabeling are so widespread because they increase pharmacy profits. Petitioners argue that because many of the infringing sales in this case were at "the generic price," [46] the pharmacists obtained no financial benefit. But pharmacies' margins of profit usually are greater on sales of generic drugs than on sales of the trademarked products.[47] Furthermore, it is now well-recognized that pharmacists often fail to pass on to consumers anything like the full cost savings they themselves realize through substitution.[48] Indeed, "the generic price" in some pharmacies may be above that charged elsewhere for the original trademarked product.[49]

Given this economic temptation, and the large number of cases in which mislabeling and illegal substitution have been proved, it is disingenuous for petitioners to claim that they could not anticipate that the "look-alike" appearance of their products would encourage these practices. Such use of "look-alikes" is inevitable, and everyone familiar with the pharmaceutical industry knows it.[50]

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[45] Affidavit of Ferdinand Bovoso (June 18, 1981).

[46] There is, of course, no such thing as "the generic price." Different generic manufacturers charge different prices, just as do different pharmacists.

[47] *Drug Product Selection: Staff Report to the Federal Trade Commission* 94 (1979); *Smith Kline & French v. Broder*, *supra*, 125 U.S.P.Q. at 302.

[48] *E.g.*, N.Y. Att'y Gen. *et al.*, *Report on New York Generic Substitution Law*, March 13, 1979, at 17-18.

[49] *See* N.Y. Att'y Gen. *et al.*, *Report*, n.48 *supra*, at 14; S. Bitterman, "Generic Drug Law Gives Stores Windfall Profits," *Miami Herald*, Aug. 13, 1978, at 1A.

[50] Although the lawfulness of petitioners' conduct under Section 43(a) of the Lanham Act is not before the Court, the evidence in this case is the same as that on which other courts have found a Section 43(a) violation. Section 43(a), 15 U.S.C. § 1125(a), for-

B. The Ruling Below Is Consistent With *Sears* and *Compco*.

The decision of the court below is in no way inconsistent with *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), in which this Court held that federal patent law preempts the power of the states to prohibit the imitation of articles not protected by patents.

First, as four circuits have held, *Sears* and *Compco* have no bearing on cases under the Lanham Act, a federal statute.[51] *Second*, as between the two federal policies implicated in this case—the policy favoring competition and the policy against trademark infringement—there is no reason to subordinate one to the other.[52] Rather, the two

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bids false designations of origin and false descriptions and representations. Two separate violations of Section 43(a) have been made out in this case.

First, these manufacturers and distributors of "look-alike" products should reasonably have anticipated pharmacists' passing off the drugs as Cyclospasmol® and are contributorily liable under Section 43(a) for this misconduct. *SK&F v. Premo, supra*, 625 F.2d at 1062, 1065-66; *Hoffmann-La Roche v. Premo, supra*, 210 U.S.P.Q. at 386.

Second, petitioners are liable for unprivileged imitation. *See SK&F v. Premo, supra*, 625 F.2d at 1062-63, 1065-66. The "look-alike" appearance of petitioners' products is not functional, as it serves no purpose but the deception of patients. See pp. 9-20 *supra*. This deception stems from the fact that consumers identify respondent's trademarked product by its size, shape and color. See pp. 10-11 *supra*. This, as well as respondent's evidence of extensive sales and promotion, establishes "secondary meaning" for purposes of Section 43(a). *SK&F v. Premo, supra*, 625 F.2d at 1063-65; *Boehringer v. Pharmadyne, supra*, 211 U.S.P.Q. at 1177-80.

[51] Pet. App. 47a-48a; *SK&F v. Premo, supra*, 625 F.2d at 1065-66; *Truck Equipment Serv. Co. v. Fruehauf Corp.*, 536 F.2d 1210, 1214 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976); *Rolls-Royce Motors Ltd. v. A&A Fiberglass, Inc.*, 428 F. Supp. 689, 692 (N.D. Ga. 1976), *interpreting Boston Professional Hockey Ass'n, Inc. v. Dallas Cap & Emblem Mfg., Inc.*, 510 F.2d 1004 (5th Cir.), *cert. denied*, 423 U.S. 868 (1975).

[52] *See FCC v. RCA Communications, Inc.*, 346 U.S. 86, 92 (1953).

policies should be reconciled, as the Second Circuit has done. Copying is in some circumstances a permissible form of competition, but it is not a permissible device to facilitate trademark infringement.[53] No issue of trademark infringement was involved in *Sears* and *Compco*. Indeed, it was not even claimed in those cases that the imitations had in any way been palmed off or substituted for the original products. Deception of purchasers, which is the heart of this case, was not involved in *Sears* and *Compco* at all.[54]

Third, in the unique context of prescription drugs, the size, shape and color of the product constitute "trade dress," which *Sears* and *Compco* protect.[55] The Court plainly contemplated that there would be some means, such as trade dress or labeling, by which a manufacturer could identify his product and distinguish it from similar products made by others (376 U.S. at 232, 238). The method of distributing prescription drugs allows no opportunity for labeling or for any form of "trade dress" other than the size, shape and color of the product itself. The manufacturer's package, no matter how distinctive in appear-

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[53] *Cf. Standard Oil Co. (Kentucky) v. Humble Oil & Ref. Co.*, 363 F.2d 945, 954 (5th Cir. 1966), *cert. denied*, 385 U.S. 1007 (1967) ("The antitrust laws require competition, not piracy * * *. There is not now, nor has there ever been, a conflict between the antitrust laws and trademark laws or the law of unfair competition").

[54] In *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 487 (1974), the Court emphasized that nothing in *Sears* or *Compco* "requires that States refrain from action to prevent * * * [commercial conduct costly to] the basic decency of society," which surely includes deception of consumers. *A fortiori*, Congress is free to act.

[55] *SK&F v. Premo*, *supra*, 625 F.2d at 1064; *Biocraft v. Merck*, *supra*, slip op. at 2; *Boehringer v. Pharmadyne*, *supra*, 211 U.S.P.Q. at 1171-72, 1174, 1178, 1183; *Hoffmann-La Roche v. Premo*, *supra*, 210 U.S.P.Q. at 382-83. In the *Boehringer* case, Premo, a petitioner here, apparently treated the appearance of its "look-alike" product as "dress." *See* 211 U.S.P.Q. at 1182. Evidently this is also the view of the consumer groups supporting petitioners as *amici*. *See* Brief *Amici Curiae* of American Ass'n of Retired Persons and National Retired Teachers Ass'n, at 3, 4, 5.

ance or conspicuously labeled, never reaches the patient. As the district court found (Pet. App. 61a) and as petitioners' *amicus* supporter NAPM concedes (Br. at 7), any imprinting on the capsules themselves would be too small to be useful, particularly for those consumers—like most users of Cyclospasmol ® and other prescription drugs[56]—with "over-fifty" eyes. *SK&F v. Premo, supra*, 625 F.2d at 1061.[57] Nothing in *Sears* or *Compco*, therefore, renders the district courts impotent to grant effective relief under the Lanham Act against "look-alikes" as a form of consumer deception.[58]

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[56] Brief *Amici Curiae* of American Ass'n of Retired Persons and National Retired Teachers Ass'n, at 2-3 n.1.

[57] For this reason, as the Third Circuit held in *SK&F, supra*, no relief in "look-alike" cases short of an injunction against copying will suffice. Certainly mere exhortations on the manufacturers' bulk packages against illegal substitution and mislabeling would be ineffectual, as the district court found (Pet. App. 61a). Petitioners' reliance on *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938), and *William R. Warner Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924), as precluding injunctions against copying is misplaced. In *Kellogg*, 97.5% of defendant's product reached consumers in distinctive packaging; no infringement of a registered trademark was established; the products were of different size, so that "no person familiar with plaintiff's product would be misled" (at 121); the shape in question was functional; and there was no evidence of passing off. Similarly, in *Warner* the chocolate that gave the product its color "serve[d] a substantial and desirable use" as a flavoring agent, "to say nothing of its effect as a suspending medium" (at 531), and thus was functional. None of this is true here.

[58] Petitioner Inwood's reliance on the First Amendment is a sham. Its advertising was not held unlawful by the court of appeals, but merely served as evidence of the Lanham Act violation: the manufacture and distribution of "look-alike" drugs with the intention or knowledge that they would be instruments of trademark infringement. The advertising simply provided additional evidence of petitioners' state of mind. The use of truthful speech to evidence a violation of law, by showing the defendant's state of mind, does not contravene the First Amendment. *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 n.3 (1965).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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January 4, 1982

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
Washington, D.C. 20201

Sep. 4, 1980

Mr. Milton A. Bass
General Counsel
Mr. George Schwartz
Executive Director
National Association of Pharmaceutical Manufacturers
747 Third Avenue
New York, New York 10017

Dear Messrs. Bass and Schwartz:

I have given careful consideration to the proposal presented in your letter of July 14 that the color, size and shape of a drug product be included as specifications in the approval of a new drug. Although I appreciate the basis for your concern, I do not believe that FDA should at this time attempt to resolve the drug product appearance issue as you propose.

As I understand the effect of your proposal, the specification of a drug product's color, size and shape in a new drug approval would link those characteristics of the drug to its generic identity. For a subsequent manufacturer to market a therapeutically equivalent product, it would, according to my understanding of the effect of your proposal, be required to duplicate the appearance of the original product.

However, I am unable to conclude that the appearance of drug products is closely enough related to their safety and effectiveness that the Agency can, on the basis of its present experience, require that generic drug products duplicate the appearance of their innovator drug counterparts. It has been the Agency's practice routinely

to approve new drug applications and abbreviated new drug applications for drug products that duplicate the color, size and shape of the innovator's product. But the Agency has not required that duplicate drug products have the same color, size and shape as the innovator product, and the Agency has not taken action affirmatively to encourage similarity in appearance between innovator products and their generic versions. As you know, there is presently controversy, including court litigation, associated with the appearance issue.

The Agency did support the Department of Justice's effort in one of those cases to promote the competitive position of less expensive generic drug products. *See Amicus* brief filed in *Smith Kline & French Company* v. *Premo Pharmaceutical Laboratories*, No. 79-2823 (3rd Cir. 1980) (copy enclosed). However, as we stated in our brief in the *Premo* case, we do not believe that the health and safety issues associated with the appearance of generic drug products prevent the competition and trademark issues from being resolved in this area as they would be in any other area. Rather, we believe that the manufacturers and distributors of drug products should be free to adopt whatever strategy they choose with respect to color, shape, and size as long as that strategy agrees with applicable law.

Thank you very much for your interest in this matter.

Sincerely yours,

/s/ Jere E. Goyan
JERE E. GOYAN
Commissioner of Food and Drugs

Enclosure

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Nos. 80-2182 and 81-11

In the Supreme Court of the United States

OCTOBER TERM, 1981

INWOOD LABORATORIES, INC., ET AL., PETITIONERS

v.

IVES LABORATORIES, INC.

DARBY DRUG CO., INC., ET AL., PETITIONERS

v.

IVES LABORATORIES, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether petitioners violated Section 32 of the Lanham Act by selling generic drugs in capsules identical to those used by respondent and by engaging in comparative price advertising.

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In the Supreme Court of the United States

OCTOBER TERM, 1981

No. 80-2182

INWOOD LABORATORIES, INC., ET AL., PETITIONERS

v.

IVES LABORATORIES, INC.

No. 81-11

DARBY DRUG CO., INC., ET AL., PETITIONERS

v.

IVES LABORATORIES, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTEREST OF THE UNITED STATES

This case raises important questions concerning the interrelationship of federal competition and trademark policies in the marketing of prescription drugs. The United States enforces federal competition policy, as expressed in the antitrust and patent laws. It also is responsible for enforcement of the Lanham Act, 15 U.S.C. 1051 *et seq.*, which prohibits trademark infringement

and certain forms of unfair competition. Moreover, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, the United States regulates aspects of the prescription drug industry, and under other federal statutes it administers and subsidizes various health care activities. As a result of these responsibilities, the United States has a particular interest in interpretations of trademark law that define fair and open competition in the prescription drug industry.

STATEMENT

Introduction

1. *Market background.* The controversy in this case focuses on the marketing and distribution of brand name and generic prescription drugs. The retail prescription drug market [1] is unusual because the article purchased is not selected by the consumer in the first instance, but by his physician. State laws require pharmacists to follow physicians' directions in filling prescriptions.[2] As a result, manufacturers of prescription drugs direct their promotional activities primarily to physicians. This is done through advertising in professional magazines and by employing "detail men" to visit doctors' offices, ex-

[1] The prescription drug market can be divided into two submarkets. The "retail" market comprises the distribution of drugs to individual consumers through pharmacies. The "institutional" market comprises the sale of drugs to hospitals and government or other agencies for distribution to patients. The controversy in this case arose from retail sales, although the relief granted covers institutional sales as well. The prescription drug industry as a whole had sales of roughly $8.5 billion in 1980. See *FDC Reports* (Mar. 9, 1981), at 15.

[2] "The physician, therefore, is the key individual in the decision-making process involving the sale of prescription pharmaceuticals." Congressional Research Service, 92d Cong., 2d Sess., *Competitive Problems in the Drug Industry: A Summary Analysis and Discussion of Issues Based on Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business* 3 (Comm. Print 1972).

plain products, and distribute free samples.[3] These promotional activities are in fact the principal source of information on new drugs for most doctors.[4] Secondary promotional efforts are directed to pharmacists to insure that they stock any products a doctor might prescribe. Little, if any, advertising is directed to consumers.

Historically, these promotional activities have been carried out almost exclusively by the larger "brand name" drug manufacturers, which also invest heavily in research and development of new drugs.[5] The major form of rivalry among these firms is product differentiation, carried out by the development of patentable products[6] and a strong emphasis on the use of tradenames rather than generic names in the promotion of prescription drugs.[7] This marketing technique, operating in a context in which physicians lack readily available information on the relative quality and prices of drugs,[8] has resulted in 90% of all prescriptions being written by brand name.[9] Price variations on therapeutically similar drugs indicate that manufacturers retain significant market power after the expiration of patents on their prescription drugs.[10]

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[3] *Id.* at 5-6, 36, 54-55.

[4] *Id.* at 54-56.

[5] *Id.* at 18-19, 54.

[6] *Id.* at 27-29.

[7] *Id.* at 39-40. Even with respect to drugs not protected by a patent, a brand name manufacturer such as Wyeth Laboratories does not promote, for example, "Wyeth's meprobamate" as superior to the thirty other brands of meprobamate. Rather, it promotes its product by its own brand name, "Equanil", and claims that it is superior to all other mild tranquilizers. *Id.* at 42-43.

[8] *Id.* at 54-59. As of the late 1960's, there were "about 4,000 different dosage forms of some 1,200 single drug entities and about 6,000 drug combination products." *Id.* at 4 (footnote omitted).

[9] *Id.* at 41, 45. In addition, most state drug substitution laws are premised on the assumption that prescriptions will refer to the brand name. See notes 11, 28, *infra*.

[10] In 1970, for example, five brand name producers sold the drug reserpine under five different trade names (Serpasil, Sandril,

In recent years the industry has undergone several changes, each of which has contributed to increased competition in the marketing of prescription drugs. First, nearly all states now have enacted drug substitution laws under which pharmacists may, under certain conditions, dispense a lower-priced generic drug even if the doctor's prescription specifies, as most do, a brand name.[11] Second, in *Virginia Pharmacy Board* v. *Virginia Consumer Council*, 425 U.S. 748 (1976), this Court struck down state-imposed restrictions on truthful advertising of retail drug prices as violative of the First Amendment. Third, the patents are or soon will be expiring on a wide variety of frequently prescribed drugs.[12] And fourth, the Food and Drug Administration has eased

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Serfin, Eskaserp, and Reserpoid). The drugs with these trade names had retail list prices ranging from $9.12 to $46.00 per thousand 0.25 mg. tablets. Eight generic producers sold the same drug with retail list prices ranging from 58 cents to $2.80 per thousand. *Id.* at 9-11. See M. Statman, *The Effect of Patent Expiration on the Market Position of Drugs* 8-13 (Nov. 15-16, 1979) (unpublished study prepared at Rutgers University for the American Enterprise Institute).

[11] *Competition in the Drug Industry: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 97th Cong., 1st Sess. 5 (1981) (*"1981 Hearing"*).

Under the New York law, for example, a doctor's prescription must indicate either "substitution permissible" or "dispense as written" (N.Y. Educ. Law § 6810.6(a) (McKinney Supp. 1981)). If substitution is permitted and the drug is on an approved state list, "[a] pharmacist shall substitute a less expensive [generic] drug product," in which event, he "shall indicate on the label * * * the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise." N.Y. Educ. Law § 6816-a.1 (McKinney Supp. 1981); cf. *id.* at § 6815.2.j (McKinney Supp. 1981).

[12] Between 1975 and 1980, the patents expired on 30 of the 100 most frequently prescribed drugs. Goldberg, "MAC's Impact: What's Really Ahead for the Drug Field? *Drug Topics* (Dec. 1, 1975), at 22. The patents on four more drugs, including Valium (the most commonly prescribed drug), will expire in 1984 and 1985. *1981 Hearing*, *supra* note 11, at 8.

requirements for the approval of generic drugs for sale (see 46 Fed. Reg. 27396 (1981)) and has formulated and published standards on drug equivalencies (see 21 C.F.R. 20.117(2)(3)).

2. *Background of this litigation.* The controversy in this case arises from the manner in which brand name and generic prescription drugs are commonly packaged for sale. Manufacturers or wholesalers sell drugs to pharmacists in bulk containers labeled with the manufacturer's name. The consumer, however, rarely sees that container. When a pharmacist fills a prescription, he transfers the prescribed number of pills or capsules from the manufacturer's container to his own, and types out his own label, which sets forth the identity of the drug, the dosage, the doctor's instructions, and, in certain circumstances under New York law, the manufacturer's name (see note 11, *supra*). Unless the state law is followed to the letter, this practice necessarily leaves room for various improper acts by pharmacists, ranging from fraudulent substitution to inadvertent trademark infringement, which, so long as the different brands are nearly identical in appearance, will rarely be noticed by the consumer. The issues in this case are whether manufacturers and wholesalers are liable for such deceptive acts by pharmacists and, if so, whether and to what extent they have an affirmative duty to prevent resulting consumer confusion.

The Parties and the Complaint

1. The drug cyclandelate, a white powder, is a peripheral vasodilator claimed to produce an increase in blood flow in patients with certain vascular diseases (C.A. App. 164a-165a).[13] The drug is sold by prescription only, and is generally taken daily for long-term therapy, primarily by the elderly (C.A. App. 237a).

For some years the respondent, Ives Laboratories, Inc. ("Ives"), has sold this drug under the registered trade-

[13] "C.A. App." refers to the joint appendix in the court of appeals. "Pet. App." refers to the appendix to the petition for certiorari in No. 80-2182.

mark CYCLOSPASMOL. Until the patent on cyclandelate expired in 1972, Ives had the exclusive right to make and sell the drug in the United States (C.A. App. 164a, 165a). Ives has marketed CYCLOSPASMOL in 200 mg. dosages in a pale blue capsule imprinted "Ives 4124" since 1962, and in 400 mg. dosages in red and blue capsules imprinted "Ives 4148" since 1975 (C.A. App. 213a-214a).

The manufacturer petitioners [14] purchase cyclandelate powder and empty capsules and assemble the product for sale to wholesalers and hospitals (C.A. App. 166a). The wholesaler petitioners sell primarily to pharmacies and physicians (*ibid.*). It has been the prevailing practice of some generic drug manufacturers for more than 20 years to market their products in the same form and color as the leading brand name manufacturers (C.A. App. 765a). In this case, all petitioners intentionally sold 200 mg. and 400 mg. capsules of cyclandelate in colors identical to Ives' CYCLOSPASMOL (C.A. App. 167a).[15] These capsules were sold in bulk containers that correctly identified the manufacturer.

The manufacturer petitioners truthfully describe their generic product to wholesalers and hospitals as "similar" or "comparable" or "equivalent" to CYCLOSPASMOL

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[14] The petitioners in No. 80-2182, Premo Pharmaceutical Laboratories, Inc. ("Premo") and Inwood Laboratories, Inc. ("Inwood"), are both manufacturers. Inwood also sells to some retail pharmacies (C.A. App. 166a). Of the additional petitioners in No. 81-11, MD Pharmaceutical Co. is a manufacturer, and Darby Drug Co., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co. ("Sherry") are wholesalers (*ibid.*). The district court in this case entered an injunction barring Sherry from using the name "Spasmol" (Pet. App. 70a); that injunction is not presented for review in this Court.

[15] Since the commencement of this litigation, Premo has begun to imprint the word "Premo" on its capsules and Inwood has imprinted "NDC 258" on its capsules. The imprints are, by necessity, very small (C.A. App. 166a).

(C.A. App. 60e-116e).[16] They also use catalogs which specify the difference in price between their generic product and CYCLOSPASMOL, which is referred to by name.[17]

2. Ives' complaint, filed in the United States District Court for the Eastern District of New York, alleges three causes of action that are relevant here: (1) that petitioners violated Section 32 of the Lanham Act, 15 U.S.C. 1114, because their look-alike capsules provide "an instrument of fraud" to retail druggists who use Ives' trademark CYCLOSPASMOL in selling capsules not manufactured by it (C.A. App. 18a); (2) that petitioners violated Section 43(a) of the Lanham Act, 15 U.S.C. 1125(a), because they used a false designation of origin in distributing their products (C.A. App. 17a); and (3) that petitioners' practices violated New York's unfair competition laws, N.Y. Gen. Bus. Law § 368-d (McKinney 1968) (C.A. App. 20a). The primary relief sought is an injunction prohibiting petitioners from marketing cyclandelate in capsules with colors identical to the colors used by Ives (*id.* at 21a).

Proceedings Below

1. *The motion for a preliminary injunction.* The district court denied Ives' motion for a preliminary injunction (Pet. App. 1a-27a), and the court of appeals affirmed (*id.* at 28a-53a). The court of appeals concluded, however, that Ives would be entitled to relief under Section 32 of the Lanham Act if it could prove, following a trial on the merits, that petitioners "suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which

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[16] Petitioners' products contain the same active ingredient as CYCLOSPASMOL. Ives has abandoned its allegations of therapeutic differences between CYCLOSPASMOL and petitioners' products (Pet. App. 62a).

[17] See C.A. App. 51e-116e.

facilitated this to a druggist whom [they] knew or had reason to know was engaging in the practices just described" (*id.* at 35a).

In addressing Ives' Section 43(a) claim, the court of appeals concluded that limitations on state unfair competition laws, established in *Sears, Roebuck & Co.* v. *Stiffel* Co., 376 U.S. 225 (1964), and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), were inapplicable to a claim under federal law (Pet. App. 47a-48a). The court also concluded that copying a nonfunctional feature,[18] which had an established secondary meaning,[19] would constitute a violation of Section 43(a) (Pet. App. 48a-49a). Finding the functionality of capsule color to be "fairly arguable" on the record before it (Pet. App. 50a), however, the court of appeals deferred to the district court's factual determination that the evidence did not warrant a preliminary injunction. The court refused to hold that colors should automatically be denied protection under Section 43(a). Instead, it left for trial the questions whether the capsule colors in this case are functional or have a secondary meaning (*id.* at 50a-51a).

2. *The Trial and Second Appeal.* Following a trial in which more than thirty witnesses testified, the district

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[18] " 'Non-functional' " features are those " 'primarily adopted for purposes of identification and individuality and, hence, unrelated to basic consumer demands in connection with the product'." Pet. App. 49a, quoting *Pagliero* v. *Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952). A feature is " 'functional' " for trademark law purposes if it is an " 'important ingredient in the commercial success of the product'." Pet. App. 49a. See *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 122 (1938).

[19] "Secondary meaning" exists when a particular feature connotes to consumers a product from a unique source. To establish secondary meaning, it is not necessary to show that consumers actually know the name of the source. It is only necessary to show that consumers reasonably believe that products bearing the feature in question derive from the same source as other products bearing that feature. See, *e.g.*, *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 118; *Fleischmann Distilling Corp.* v. *Maier Brewing Co.*, 314 F.2d 149 (9th Cir. 1963).

court dismissed Ives' claims in their entirety (Pet. App. 54a-70a). The district court concluded that Ives once again had failed to prove any contributory trademark infringement in violation of Section 32—*i.e.*, Ives failed to prove that petitioners suggested "even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark CYCLOSPASMOL. Nor did Ives show that [petitioners] continued to sell the generic drug to pharmacists who [petitioners] knew or had reason to know were engaging in such a practice" (Pet. App. 59a). Since petitioners did not "detail" their products through sales representatives, any implied or explicit suggestion to misuse the mark CYCLOSPASMOL could stem only from their catalogs and promotional material (C.A. App. 51e-116e), which the court found "cannot fairly be read as suggesting to druggists that they affix Ives' mark to bottles containing [petitioners'] capsules" (Pet. App. 59a). Similarly, it concluded that the evidence was insufficient to establish that petitioners knew of wide-spread infringement by pharmacists because (1) mislabeling did not occur with significant frequency and (2) to the extent that mislabeling did occur, it was due primarily to a misunderstanding by druggists of the precise requirement of the New York Drug Substitution Law (Pet. App. 59a-60a).[20]

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[20] At trial, Ives offered evidence of two types of violations by pharmacists. First, there were instances of illegal substitution accompanied by mislabeling. In those instances, doctors had prescribed CYCLOSPASMOL, to be dispensed as written, and the pharmacists illegally substituted a generic product and mislabeled it as CYCLOSPASMOL. Ives proved only 15 such occurrences. Its evidence derived from test purchases from pharmacists "selected from shops at the suggestion of employees of Ives because they thought these pharmacies might be making illegal substitutions in filling prescriptions for CYCLOSPASMOL" (C.A. App. 165a, 170a-171a, 833a; Pet. App. 36a).

Second, there were instances of simple mislabeling. Of a sample of 83 pharmacists who filled prescriptions permitting substitution, 35 pharmacists dispensed generic cyclandelate. Of these 35, only ten used the word "CYCLOSPASMOL" on the label (C.A. App. 536e). Of those ten, however, five modified the trademark with some form

Addressing Ives' Section 43(a) claim, the district court held that capsule color copying could be barred only if Ives proved that its colors had acquired a secondary meaning and that they were not functional (Pet. App. 62a). It found that the colors were functional for several reasons. First, the court found that because many patients—particularly users of cyclandelate—associate the appearance of their medication with its therapeutic effect, some will refuse drugs with different coloring while others, although accepting the new colored drugs, suffer "considerable anxiety and confusion by the change." *Id.* at 63a. Second, the court found that patients frequently commingle their drugs in a single container, relying only on color to follow their doctor's instructions. *Ibid.* Third, the court found that color was useful in certain emergency situations in identifying drug overdoses. *Ibid.* Finally, the functional aspects of color were demonstrated by the insistence of some hospitals, pharmacies, and wholesalers on receiving drugs of the same color in order to minimize administrative confusion within those organizations. *Id.* at 63a-64a.

Even assuming capsule color to be nonfunctional, the district court also found that Ives had failed to establish secondary meaning in accordance with *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 118. It credited the views of several doctors who testified that "patients do not associate the appearance of a drug capsule with the manufacturer or other source but with the drug's effect on the patient's disability" (Pet. App. 65a). The court also found that Ives' survey, which attempted to show that patients associate Ives' capsule colors with CYCLOSPASMOL, was wholly inadequate to establish secondary meaning. The court concluded that the survey was significant not because many patients identified colored cap-

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of the word "generic." And nine of the ten responded to an inquiry whether they had the generic drug in stock by truthfully stating that the prescription had been filled with a generic product. Only one pharmacist charged the brand name price for the generic drug (C.A. App. 942e-976e; Pet. App. 60a).

sules as CYCLOSPASMOL, but because so few patients were able to do so (Pet. App. 66a).[21] Moreover, the court found that even among those patients who did recall the word CYCLOSPASMOL, the survey did not show that patients associated the trademark with a single manufacturer as opposed to the therapeutic qualities of cyclandelate. *Id.* at 66a-67a.[22]

On appeal, a divided panel of the court of appeals reversed, concluding that "the undisputed evidence establishes a violation of § 32" (Pet. App. 74a-75a).[23] The court found the evidence of pharmacist mislabeling to be more significant than did the trial court (*id.* at 81a-82a). The majority also took judicial notice of the issuance of six indictments against druggists in the metropolitan New York area for illegal substitution in violation of state law (*id.* at 84a).[24] While acknowledging that it should not prejudge the guilt or innocence of the pharmacists in those cases, the court nevertheless found these indictments to be sufficient to show "that illegal substitu-

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[21] This survey showed that approximately one-third of those patients taking CYCLOSPASMOL did not recall the name without prompting and another one-third of the patients could not even recognize the word among a group of ten wholly dissimilar trade names. C.A. App. 139e-152e, 372e, 529e.

[22] The district court found Ives' state law claim to be equally without merit. The court concluded that the policies of New York's unfair competition law, which protects consumers from deception, must be weighed against the policies of New York's drug substitution law, which encourages generic drug use. After balancing these conflicting public policies, the court dismissed Ives' state law claim. Pet. App. 69a-70a.

[23] In view of its holding that petitioners violated Section 32, the court of appeals declined to express any view on the claims brought under Section 43(a) or under New York's unfair competition laws. Pet. App. 75a.

[24] These indictments were returned after the trial in this case and were not brought to the attention of the district court. New York State has 15,000 pharmacists and at least 3,000 pharmacies (C.A. App. 766a, 537e-538e; see Pet. App. 89a).

tion and mislabeling in New York are neither *de minimis* nor inadvertent" (*id.* at 83a).

The court also dismissed petitioners' functionality arguments as "unconvincing." The court expressed the belief that anxiety and confusion associated with changes in capsule color are minimal and easily "cured by explaining the change to the patient," and noted the lack of patient testimony to the contrary (Pet. App. 85a). It further reasoned from this premise that, because no functional justification exists for duplicating capsule color, "the inference is inescapable that [petitioners'] use of identically-colored, shaped and sized capsules was in anticipation that they would successfully capitalize upon public acceptance of CYCLOSPASMOL by reason of the fact that at least a substantial number of druggists would either substitute the generic product illegally or mislabel it as CYCLOSPASMOL" (*ibid.*).

Judge Mulligan dissented. He concluded that Ives' evidence was totally inadequate to show widespread substitution or trademark infringement by pharmacists, and certainly was insufficient to show that the petitioners knew or had reason to know of such practices (Pet. App. 87a-89a). He also emphasized that petitioners' juxtaposition of brand and generic names in catalogs was a common and necessary trade practice and that the district court's finding of functionality was not clearly erroneous (*id.* at 90a-91a).

3. *The remedy ordered in the district court.* On remand, the district court held that it was constrained by the court of appeals' mandate to enjoin petitioners' use of Ives' colors for generic cyclandelate (Pet. App. 98a). Moreover, since the court of appeals' decision implied that an intentional violation had occurred, the district court concluded that it must allow Ives to recover damages as well as any profits earned by petitioners through their unlawful actions (*id.* at 100a).

INTRODUCTION AND SUMMARY OF ARGUMENT

This case raises important questions concerning the proper interpretation of the Lanham Act. It involves the delicate interplay between two public policies—one favoring competitive product imitation, the other favoring the use of trade symbols to identify source or origin. Both of these policies seek to promote fair and efficient competition. Trademark law is premised on the belief that manufacturers should have the ability to identify products as their own so as to benefit from favorable customer experience; else they will have little incentive to invest in product quality features as a means of gaining consumer recognition. However, if new entrants are barred from using features which have value to consumers—other than as identifications of source—then those firms will be unduly hampered in their efforts to engage in the competitive process. For the reasons set forth below, we submit that the court of appeals failed to balance these factors correctly, and thus erred in finding deliberate contributory infringement under Section 32 of the Lanham Act.

I.

Analysis of the doctrine of contributory infringement, recognized under Section 32 of the Lanham Act, requires a balancing of the procompetitive effect of trademarks in identifying products for consumers and the anticompetitive effect of raising barriers to market entry by forbidding imitation. As a rule of vicarious liability, contributory infringement holds a manufacturer responsible for illegal acts committed by his customers—or by others more remote in the distribution chain—over whom he may have little direct control. It does not, however, establish a regime of strict liability. Under the standards enunciated by Judge Friendly in the first appeal in this case, and nominally applied by the majority in the second appeal, an essential element of contributory infringement under Section 32 is a showing of active inducement or knowledge of wrongdoing. This rule, requiring a guilty state of mind, has a sound basis in the common law antecedents of the Lanham Act.

The state of mind requirement is not merely a rule of fairness: it serves an essential public policy. No legitimate competitive policies are impaired by requiring manufacturers to refrain from *actively* encouraging trademark infringement, or to refrain from selling to individual customers they know or have reason to know are engaged in such illegal practices. Accordingly, in these limited circumstances, the public interest in an efficient competitive system is best served by requiring manufacturers to take reasonable remedial steps, such as differentiating their product or monitoring their customers. On the other hand, where, as here, only a few unscrupulous retailers out of many are engaged in trademark violations, the public interest balance is quite different. In such a case, the cost of barring imitation outweighs the marginal benefit to trademark interests. As this Court noted in an analogous context in *Kellogg Co.* v. *National Biscuit Co., supra*, 305 U.S. at 121, the intent of the law is not "to insure that every purchaser will know * * * the maker," but rather to insure the use of "reasonable means to prevent confusion." Such "reasonable means" must be proportionate to the magnitude of the problem and consistent with the right to compete.

The court of appeals did not properly weigh these countervailing interests under Section 32 and, accordingly, erred on the side of overdeterrence. The evidence showed only isolated instances of unambiguously deliberate infringement by pharmacists. The record here was far less compelling than in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980 (D. Mass. 1946), aff'd, 162 F.2d 280 (1st Cir.), cert. denied, 332 U.S. 809 (1947), where no violation was found. Moreover, on the factual issue of functionality, disputed at trial with sharp evidentiary conflicts, the court of appeals gave insufficient deference to the findings of the district court. See Fed. R. Civ. P. 52(a).

II.

Although the court of appeals did not reach respondent's Section 43(a) claims, it is that provision, rather

than Section 32, which is at the heart of the present controversy. In our view, the fundamental issue in this case is whether capsule color imitation itself constitutes a misrepresentation as to source or origin. The trademark infringement issue decided by the court of appeals is merely peripheral to this more fundamental question. In the event that the holding of the court of appeals under Section 32 is reversed and the case is remanded for consideration of respondent's Section 43(a) claims, it would be appropriate for this Court to establish guidelines for the lower courts. Those guidelines can be framed in a manner that reflects a proper balancing of the public interests involved in this case.

It may well be that the unusual aspects of the prescription drug market—a market in which manufacturers do not address themselves through advertising or promotion to the ultimate consumer—will make it more difficult to establish product and source identity than in other markets. Accordingly, it is essential to avoid articulating standards in this context that would make it unduly difficult for manufacturers in other fields to reap legitimate rewards for producing a product that has strong consumer recognition.

III.

In any event, the injunctive and monetary relief awarded by the district court are far more expansive than the record warrants. See *Hartford-Empire Co.* v. *United States*, 323 U.S. 386 (1945); *Kellogg Co.* v. *National Biscuit Co., supra; William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526 (1924). The record in this case fails to support an injunction barring petitioners from marketing their products in blue and blue-red capsules identical to those used by Ives. In most instances, proper labeling is sufficient to prevent consumer confusion (see *Kellogg Co.* v. *National Biscuit Co., supra*). Even if, as found by the district court, labeling individual capsules will not avoid potential confusion, there may exist far less restrictive alternatives than a total ban on color imitation.

ARGUMENT

I. THE COURT OF APPEALS ERRED IN FINDING CONTRIBUTORY INFRINGEMENT OF RESPONDENT'S TRADENAME "CYCLOSPASMOL" ON THE BASIS OF PETITIONERS' CAPSULE COLOR COPYING AND COMPARATIVE ADVERTISEMENTS

A. A finding of contributory infringement under Section 32 of the Lanham Act requires proof of guilty knowledge

The legal standard for contributory infringement nominally applied by the court below is that "a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described" (Pet. App. 78a, quoting Judge Friendly's earlier opinion in this case (emphasis omitted)). While that articulation is generally correct, it fails to highlight the importance of the state of mind requirement in contributory infringement cases. And in any event, the court of appeals erred in applying that standard to the record in this case.

Although Section 32 creates strict liability for persons who actually infringe a trademark, the doctrine of contributory infringement is a judicial construction based on the common law principle that a person may be held vicariously liable for the trademark infringement of another person only upon a showing of a guilty state of mind. Judge Friendly's reference (Pet. App. 35a) to *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980, 989 (D. Mass. 1946), indicates that the Second Circuit recognizes that a state of mind requirement exists in actions for contributory infringement.

In the *Snow Crest* case, bartenders had used Snow Crest's cola beverage instead of Coca-Cola's beverage in

mixed drinks. Snow Crest's manufacture of a product identical in appearance to that of Coca-Cola, it was claimed, constituted contributory infringement. Judge Wyzanski rejected this claim, noting that the supplier would not be liable unless he had "knowledge that the [bartenders] will or can reasonably be expected to commit a tort with the supplied instrument." 64 F. Supp. at 989. He observed, moreover, that "any man of common sense knows that in any line of business * * * there are some unscrupulous persons who, when it is to their financial advantage to do so, will palm off on customers a different product from that ordered by the customer" (*id.* at 988-989). This, however, does not establish contributory infringement. There must be more—either active encouragement of infringement or continued sales to particular customers whom the manufacturer knows or should know are engaged in improper "palm[ing] off." *Id.* at 989.[25]

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[25] "Palming off" refers to deliberate misrepresentation of the source of a product, as, for example, through misapplication of a trademark. In the present case, the district court found that instances of trademark misapplication were inadvertent infringements resulting from pharmacists' failure to understand statutory labeling requirements. See Pet. App. 60a.

This Court has referred to the state of mind requirement in cases involving "palming off" by customers of manufacturers. For example, in *FTC* v. *Winsted Hosiery Co.*, 258 U.S. 483, 493 (1922), a case arising under Section 5 of the FTC Act, Justice Brandeis stated that the false labels on respondent's products were "calculated to deceive and do in fact deceive a substantial portion of the purchasing public." In *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 530, a private unfair competition case, the Court observed that "some of petitioner's salesmen suggested that, without danger of detection, prescriptions and orders for Coco-Quinine could be filled by substituting Quin-Coco. More often, however, the feasibility of such a course was brought to the mind of the druggist by pointing out the identity of the two preparations and the enhanced profit to be made by selling Quin-Coco because of its lower price." In instances where it was found that the defendant's agents had "induced the substitution, either in direct terms or by suggestion or insinuation," the Court held that "[t]he wrong was in

In articulating this standard, Judge Wyzanski relied in substantial part on long-established common law principles of vicarious liability, drawing on such sources as the *Restatement of Torts*. 64 F.Supp. at 989. The provisions of the *Restatement* relied on by Judge Wyzanski fully support the rule that he applied.[26]

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designedly enabling the dealers to palm off the preparation as that of the respondent." *Ibid.* (citations omitted). The lower courts have adopted a similar rule requiring active inducement in cases involving claims of wrongful product imitation. See, *e.g.*, *Smith, Kline & French Laboratories* v. *Clark & Clark*, 157 F.2d 725, 731 (3d Cir. 1946); *Upjohn Co.* v. *Schwartz*, 246 F.2d 254 (2d Cir. 1957); *NuGrape Co.* v. *Glazier*, 22 F.2d 596 (5th Cir. 1927); *Famolare, Inc.* v. *Melville Corp.*, 472 F. Supp. 738, 746 (D. Hawaii 1979).

[26] Section 714 provides (III *Restatement of Torts* 551 (1938)):

> One fraudulently markets his goods as those of another if, though making no misrepresentation himself, he intentionally induces his purchasers so to market them.

Section 302, Comment M, provides (II *Restatement of Torts* 821-822 (1934)):

> The actor is required to realize the likelihood of intentional intermeddling only if he creates a situation or does an act, which affords a temptation to, or an opportunity for, intermeddling by a person or class of persons whom he knows or should know to be peculiarly likely to do so. Thus, if the actor's conduct is intended or likely to create a situation which may do harm if third persons meddle with it, in a place which he should know is likely to be frequented by children without their parents, the actor should recognize the situation as dangerous, although it would be sufficiently safe were the place likely to be frequented only by adults * * *.

In addition, see Section 738, illustration 1, which provides (III *Restatement of Torts, supra*, at 619):

> A manufactures and markets goods under the trade name "Manou." B sells similar goods to wholesalers. While not deceiving them, he advises them to sell the goods as the "Manou" brand. He also sends agents to retailers to advise them to do the same. Both the wholesalers and the retailers do offer B's goods for sale as the "Manou" brand. In each instance B infringes A's trade name.

No conduct or state of mind of this sort was proven in the present case.

Such a rule is, moreover, fully consistent with the objectives of the Lanham Act, in which Congress declared its intent to make actionable "the deceptive and misleading use of marks * * *; to prevent * * * unfair competition; [and] to prevent fraud and deception * * * by the use of reproductions, copies, counterfeits, or colorable limitations of registered marks." 15 U.S.C. 1127. See S. Rep. No. 1333, 79th Cong., 2d Sess. 5 (1946). This language hardly suggests that federal judges, in recognizing remedies for "contributory infringement" that are not specifically prescribed by Congress, should dispense with the state of mind requirement traditionally applied at common law. See generally, *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185 (1976).

The record in this case does not establish the existence of a state of mind sufficient to predicate liability under Section 32. The only evidence on which the court of appeals relied was the fact that some passing off by pharmacists had occurred, that the capsules were identical, and that petitioners had engaged in comparative price advertising and made specific reference to Ives' products. Such evidence is insufficient to establish either that petitioners were actively involved in any deception, or that they sold to particular pharmacists that they knew or should have known were engaged in infringement.

B. Petitioners are not responsible for the isolated acts of "palming off" disclosed by this record

Neither court below found that petitioners made any direct suggestion, orally or in writing, that would induce a pharmacist to infringe the tradename CYCLOSPASMOL.[27] At most, the court of appeals was able to infer

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[27] Violation of Section 32 must be predicated on infringement of the trademark rather than causing confusion as to the origin of the product. Confusion as to origin is the gravamen of a claim under Section 43(a). See pages 24-30, *infra*. The 1962 amendments to the Lanham Act clearly demonstrate this distinction. Section 32 was amended to delete language referring to deception

that capsule color copying and comparative advertising increased the likelihood that some pharmacists would misuse the tradename CYCLOSPASMOL. That conduct is far more innocuous than the conduct considered by this Court in *Winsted* and *William R. Warner*. See note 25, *supra*. And the result reached by the court of appeals in this case cannot be squared with the holding in *Snow Crest*, *supra*, 64 F. Supp. at 988-989.

Similarly, neither court below suggested that petitioners sold their products to specific pharmacies they knew or had reason to know were engaged in passing off. The court inferred the requisite intent or knowledge solely because petitioners could "reasonably anticipate" that "a substantial number of druggists" would engage in illegal conduct (Pet. App. 82a) and because it believed that petitioners "have not offered any persuasive evidence of a legitimate reason" for using look-alike capsules (*id.* at 84a). The former ground rests on the reasoning that was correctly rejected in *Snow Crest*. Absent active inducement or knowledge of a particular customer's propensities, a "defendant's accountability for his customer's wrongful use of [a] product turns on the issue whether a reasonable person in the defendant's position would realize * * * that he himself had created a situation which afforded a temptation to or an opportunity for wrong" (64 F.Supp. at 989.). The record in this case shows no active inducement or irresistible temptation to the honest pharmacist, nor does it show pervasive illegality by pharmacists. Instead, the panel majority substituted its judgment for that of the district court simply because the isolated instances of substitution and mislabeling were, in its view, "neither *de minimis* nor inadvertent" (Pet. App. 83a).[28]

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concerning "source of origin," while similar language was retained in Section 43(a). Act of Oct 9, 1962, Pub. L. No. 87-772, Section 17, 76 Stat. 773. See S. Rep. No. 2107, 87th Cong., 2d Sess 25 (1962).

[28] In fact, the record is consistent with the conclusion of Judge Mulligan and the district court that the pharmacists simply did

The alternative basis for the majority's inference of guilty knowledge, and the apparent key to its finding of contributory infringement, was a summary rejection of the district court's factual finding that the capsule colors had functional value—*i.e.*, the colors served some commercial or competitive purpose other than representing source.[29] Since it did not believe that color copying could have a functional purpose, the majority concluded that petitioners' only possible motive for color copying was to induce or facilitate "palming off." Even if one were to assume nonfunctionality and clear error by the district court on this factual issue, however, the majority's reasoning contains a logical gap. It is quite possible that petitioners, relying on intuition, anecdotal evidence, or

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not understand the statutory labeling requirements. See page 9 & note 20, *supra*. Indeed, the state substitution laws are based on the implicit premise that doctors and pharmacists communicate with each other by reference to tradenames, even in prescribing generic products. It is understandable that pharmacists will attempt to communicate with their customers in the same language (see C.A. App. 1098a-1101a). Under such circumstances, technical and isolated violations of the trademark laws by pharmacists do not support an inference of an intent to defraud, much less knowledge of pharmacists' fraud by the generic manufacturers. Moreover, since only one out of the group of pharmacists surveyed by Ives failed to admit that he was dispensing a generic product and charged the brand name price (see note 20, *supra*), the evidence refutes the court of appeals' conclusion that a significant number of pharmacists are engaged in intentional deception or profiteering.

Even if one were to go beyond existing law and to impute "guilty knowledge" to a manufacturer who knows that some of his customers might "palm off," yet takes no preventive measures, such a rule would be inapplicable here. In the context of the prescription drug industry, inexpensive alternatives may not have been available to generic manufacturers. As the district court found, labeling each capsule would be ineffective to disclose source. Although prepackaging capsules in consumer-size doses might be feasible, there is no sound basis for imputing "guilty knowledge" to a manufacturer simply because he failed to pursue that novel, and potentially costly, alternative.

[29] See page 10, *supra*.

considered business judgment, actually believed, even if erroneously, that the colors were functional—*i.e*, served purposes other than representation of source. Given this possibility—and given the evidence showing the functional aspects of color in this market—the record in this case does not support the court of appeals' inference of bad faith on the part of the generic manufacturers.[30]

C. The court of appeals' ruling could chill truthful advertising and legitimate competitive behavior

Important public policies mandate rejection of claims of contributory infringement based on comparative advertising. The use of another person's tradename in comparative advertising is protected speech. Competitors "have a right to tell the public what they are doing and to get whatever share they can in the popularity of [a given product] by advertising that they are trying to make the same article and think that they succeed. * * * By doing so they are not trying to get the good will of the name, but the good will of the goods." *Saxlehner* v. *Wagner*, 216 U.S. 375, 380-381 (1910). Moreover, the free availability of comparative price information is not merely tolerated, but is central to our competitive econ-

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[30] Indeed, the panel on the earlier appeal had found the issue of functionality to be "fairly arguable." Pet. App. 50a. The generic manufacturers apparently began copying the capsule colors of the brand name manufacturers long before they had any significant retail market. At that time, they were limited primarily to institutional markets. See C.A. App. 765a; Congressional Research Service, 92d Cong., 2d Sess., *Competitive Problems in the Drug Industry: A Summary Analysis and Discussion of Issues Based on Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business* 6-7 (Comm. Print 1972). In this context, they would have little incentive to prepare products for the purpose of passing off, since their hospital and government purchasers certainly were well aware of their sources. Moreover, as noted earlier, there was evidence in the record that some hospital and institutional purchasers expressed a preference for color uniformity, and that color served a significant function apart from identifying the source. See page 10, *supra*.

omy. *National Society of Professional Engineers* v. *United States*, 435 U.S. 679, 692-693 (1978). Even with respect to potentially hazardous products, this Court has held that the antitrust laws protect truthful advertising of prices against suppression at the behest of private parties (*id.* at 695-696), and that the First Amendment protects such advertising against undue governmental prohibitions. *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 363-365 (1977); *Virginia Pharmacy Board* v. *Virginia Consumer Council*, 425 U.S. 748, 761-765 (1976). Whatever incidental effect petitioners' truthful advertising may have in increasing the possibility of infringement, to use that advertising as a basis for liability under Section 32 would needlessly impair competition. Since dishonest retailers are fully capable of seeing the opportunities for fraud without referring to comparative advertising (*Snow Crest*, *supra*, 64 F. Supp. at 988-989), the chilling effect of the majority's ruling on legitimate product imitation is not offset by significantly greater compliance with the trademark laws.

It follows from the foregoing that the court of appeals has not properly weighed the relevant interests in this case. To be sure, when pharmacists engage in infringement, their conduct is not to be condoned;[31] but the offending pharmacists are not before this Court. The question in this case is whether the generic manufacturers—who clearly marked their bulk containers with proper indicia of origin and who themselves engaged in no infringement or active inducement—must suffer broad injunctions, disgorgement of profits, and, perhaps, treble damage awards for the isolated misdeeds of a few self-serving retailers. Consistent with this Court's statement in *Kellogg* that the purpose of the law is not "to insure that every purchaser will know * * * the maker,"

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[31] Our national competition policy, as expressed in the Lanham Act and the antitrust laws, promotes fair competition in which sellers have incentives to identify and differentiate their products.

but only to require "every reasonable means to prevent confusion" (305 U.S. at 121), it is a question that, on this record, must be answered in the negative.

In this regard, the Court's admonitions in *United States* v. *United States Gypsum Co.*, 438 U.S. 422 (1978), are pertinent.[32] Where prohibited behavior is "difficult to distinguish from the gray zone of socially acceptable and economically justifiable business conduct," courts should refrain from imposing rules which may result in "over-deterrence" (*id.* at 441). This is true because (*ibid.*; footnote omitted):

> salutary and procompetitive conduct lying close to the borderline of impermissible conduct might be shunned by businessmen who chose to be excessively cautious in the face of uncertainty regarding possible exposure to criminal punishment for even a good-faith error of judgment.

II. THIS CASE SHOULD BE REMANDED SO THAT THE COURT OF APPEALS CAN REVIEW THE DISTRICT COURT'S RULING WITH RESPECT TO SECTION 43(a) OF THE LANHAM ACT

Unlike Section 32, which focuses on misuse of trademarks, Section 43(a) of the Lanham Act contains a more general prohibition of unfair competition—*i.e.*, a prohibition of marketing techniques that create confusion as to source or origin. The court of appeals did not address the Section 43(a) claim in its decision following the trial on the merits in this case. Under Judge Friendly's earlier opinion, however, Ives could not bar capsule color copying unless it proved that the color in question had a "secondary meaning." Thus, Ives was required to prove

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[32] Although the Court limited its holding in *Gypsum* to the criminal antitrust case before it (438 U.S. at 436 n.13), its reasoning is applicable here. This is particularly true of the Court's observation that "where the conduct proscribed is difficult to distinguish from conduct permitted and indeed encouraged, * * * the excessive caution spawned by a regime of strict liability will not necessarily redound to the public's benefit" (*id.* at 442 n.17).

that consumers associated the capsule color with a single source, though the consumers need not be able to identify that single source.[33] Even if it proved "secondary meaning," moreover, Ives could not bar copying if the color had "functional" value, which Judge Friendly defined as value apart from identifying the product with a particular source (Pet. App. 63a-67a). Thus, a defendant could be held liable only if it copied the "nonfunctional" features of another person's product and if, in addition, those features had acquired a "secondary meaning" (*id.* at 48a-49a). This analysis reflects the prevailing rule that a manufacturer must prove secondary meaning, *i.e.*, consumer identification of certain product features with a particular, if unidentified, source, in order to protect those features from imitation.[34]

In the decision here under review, the court of appeals did not reach the issue of secondary meaning. However, it summarily rejected petitioners' evidence of functionality as "unconvincing" (Pet. App. 84a-85a). Because respondents' Section 43(a) claim may be urged as an alternative ground for affirmance in this Court, and because, in any event, the claim must be considered by the court of appeals on remand, we consider it appropriate to briefly discuss that claim.

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[33] See pages 10-11 & note 19, *supra*.

[34] See, *e.g.*, *Fisher Stoves, Inc.* v. *All Nighter Stove Works, Inc.*, 626 F.2d 193, 194-195 (1st Cir. 1980); *Keebler Co.* v. *Rovira Biscuit Corp.*, 624 F.2d 366, 378 (1st Cir. 1980); *O'Day Corp.* v. *Talman Corp.*, 310 F.2d 623, 624-625 & n.2 (1st Cir. 1962), cert. denied, 372 U.S. 977 (1963); *Vibrant Sales, Inc.* v. *New Body Boutique, Inc.*, 652 F.2d 299, 303 (2d Cir. 1981); *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1065 (3d Cir. 1980); *West Point Manufacturing Co.* v. *Detroit Stamping Co.*, 222 F.2d 581, 589-590 (6th Cir.), cert. denied, 350 U.S. 840 (1955); *Truck Equipment Service Co.* v. *Fruehauf Corp.*, 536 F.2d 1210, 1215 (8th Cir.), cert. denied, 429 U.S. 861 (1976); *Vuitton et Fils S.A.* v. *J. Young Enterprises, Inc.*, 644 F.2d 769, 772 (9th Cir. 1981).

A. Colors with secondary meaning convey significant information to consumers

The district court found that Ives had failed to establish that the capsule colors in this case had become publicly identified with a particular source (Pet. App. 64a-67a). In view of the manner in which prescription drugs are marketed, it is not surprising that the district court found that Ives had failed to establish secondary meaning. As the district court noted: "Ives' failure of proof highlights the difficulty of proving secondary meaning to consumers in the prescription drug market" (*id.* at 68a). The promotion of prescription drugs is necessarily directed chiefly to physicians, "[b]ut extensive promotion to physicians does not establish that they have passed along to their patients any message as to source. For that reason, secondary meaning will perhaps be difficult to establish in these prescription drug cases where the patient never sees the manufacturer's packaging" (*id.* at 68a-69a). Indeed, the district court may well have understated the matter, for the color of an item is not a feature to which one necessarily looks for an indication of source, and Ives' evidence suggests that even drug nomenclature is a mystery to most consumers.[35]

It should be recognized, however, that a finding that Ives failed to prove secondary meaning for its capsule colors does not preclude other manufacturers from establishing secondary meaning in specific capsule colors if they are capable of proving the requisite association in

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[35] Ives' sole evidence of secondary meaning was a consumer survey of patients for whom CYCLOSPASMOL had been prescribed. It showed that one-third of the patients spontaneously identified petitioners' capsules as CYCLOSPASMOL, and another third, who had been unable to identify them initially, were able to pick CYCLOSPASMOL from a list of ten dissimilar brand names for various drugs. The final third were unable to identify the capsules even from a list. See note 21, *supra*. That survey, however, did not seek to establish whether the patients recognized that CYCLOSPASMOL was a tradename, or otherwise indicated a source of origin for the drug.

the minds of consumers. As Judge Friendly noted (Pet. App. 50a), earlier cases which rejected, as a matter of law, the concept that secondary meaning may inhere in a color are outdated, and in any event reflect an unawareness of the utility of product differentiation as a means of avoiding consumer confusion.[36] Modern technology is capable of producing myriad colors, shades, and combinations.[37] If drug manufacturers should, in the future, choose to advertise or otherwise establish secondary meaning in specific capsule colors, and those colors are found to be nonfunctional in the context of the particular case, no social policy would be served by denying the manufacturers the protection afforded under Section 43(a) of the Lanham Act.

Moreover, in a case such as this, arising in the prescription drug market, care must be taken to avoid allowing governing legal principles to be distorted by the unusual characteristics of a market in which manufacturers and ultimate consumers are remote from one another. The protections Congress intended under Sec-

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[36] Nonfunctional product features that have acquired a secondary meaning serve the same purpose as trademarks in identifying source to consumers, and in so doing they promote competitive objectives. As Congress noted in passing the Lanham Act (S. Rep. No. 1333, 79th Cong., 2d Sess. 4 (1946)):

> Trade-marks, indeed, are the essence of competition, because they make possible a choice between competing articles by enabling the buyer to distinguish one from the other. Trademarks encourage the maintenance of quality by securing to the producer the benefit of the good reputation which excellence creates. To protect trade-marks, therefore, is to protect the public from deceit, to foster fair competition, and to secure to the business community the advantages of reputation and good will by preventing their diversion from those who have created them to those who have not.

See generally McClure, *Trademarks and Unfair Competition: A Critical History of Legal Thought*, 69 Trademark Rep. 305 (1979).

[37] See Cooper, *Trademark Aspects of Pharmaceutical Product Design*, 70 Trademark Rep. 1, 22-27 (1980).

tion 43(a) should remain fully available to manufacturers in consumer-oriented markets who, by their commercial ingenuity, succeed in investing their products with secondary meaning having informational value to the consuming public.

B. Claims that colors have functional value require careful scrutiny

Should the court of appeals, on remand, set aside the district court's findings on secondary meaning as clearly erroneous, it will then be required to determine that the capsule colors here involved are not functional before it may ban color imitation. As indicated above, the majority opinion simply dismissed the district court's findings of functionality without any analysis. We submit that a more discriminating treatment of this question is called for, particularly in view of the existence in this case of two distinct consumer submarkets: retail and institutional purchasers.

The district court's first finding of functionality was that the colors had commercial significance to individual consumers because the colors had come to symbolize the "therapeutic effects" of the drug cyclandelate. Thus, "some patients may be fearful and offer resistance if their accustomed medicine is dispensed in a different color" (Pet. App. 22a). Deeming color to be functional merely because it allays consumer anxiety, however, is somewhat anomalous. Such analysis is based on the paternalistic notion that, in order to avoid irrational action by consumers, a change in source should be *concealed* from them. We strongly question the propriety of such an approach in an economic system designed to maximize *informed* consumer choice.

Under existing laws, consumers are not allowed to select prescription drugs themselves. If they have a question about the use of a new color capsule for their medicine, their doctors or dispensing pharmacists are available to explain it. The district court's reasoning assumes that consumers are unable to react rationally to such an ex-

planation. That assumption, however, reflects the type of "paternalistic approach" to drug marketing that this Court rejected in *Virginia Pharmacy Board* v. *Virginia Consumer Council*, *supra*, 425 U.S. at 770. As the Court noted in that case, the better assumption is "that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." *Ibid.*

The danger perceived by the district court is that some consumers might perceive a change in capsule colors to mean that the new medicine is not as effective as the original medicine. But there is no reason to believe, absent clear evidence to the contrary, that any such incorrect impressions cannot be cured readily by doctors or pharmacists responding to patient inquiries. Different colors will often lead consumers to inquire, and they then can make an informed decision. Conversely, unrestricted imitation of capsule colors may interfere with the communication to consumers of information about source of origin. Consequently, we submit that absent any *other* functional effects attributable to capsule color copying, it would be contrary to public policy to allow copying of capsule colors which have attained secondary meaning solely to protect a few persons from making a choice based on irrational anxiety rather than medically significant facts.

The district court did find, however, that capsule color imitation has several functional benefits apart from avoiding consumer anxiety. There was evidence that some patients placed various medicines in a single container and relied on capsule colors to identify the pill they must take at a specific time—*e.g.*, "I take the red one at six o'clock." See C.A. App. 367a-369a. Similarly, there was evidence that when overdose victims are unable to inform physicians of the identity of the drugs taken, capsule colors may help physicians to identify the

drug involved. See *id.* at 1025a-1027a, 1138a-1141a. While reliance on capsule color for these two purposes is far from optimal from the perspective of health care, the test of "functionality" would be satisfied if they were important to a significant group of consumers. On the other hand, color imitation would not be commercially significant, *i.e.*, would not meet the test of functionality, if only a few patients mix their medications in a single container and rely on color to identify medicinal properties. By the same token, there would be little commercial or competitive significance if the identities of drugs taken in overdose situations are ascertained by capsule color only in rare instances. Color should not be deemed functional for the foregoing reasons unless there is evidence that, to obtain such benefits, a significant number of physicians or patients would prefer a medicine because it is dispensed in a particular colored capsule.

The district court's finding of functionality based on resistance by hospitals and retail pharmacies to purchasing drugs in capsules of different colors (Pet. App. 63a-64a) also turns on evidence that is rather sparse. There is evidence that some hospitals would prefer to purchase a generic drug in the same color capsule as the name brand in order to lessen the likelihood of confusion in the dispensing of medication. Compare C.A. App. 1269a-1275a, 1431a, 686e-688e, 706e-707e, 710e, 713e, with 797a, 1034a-1035a, 1145a-1146a, 1332a, 1428a-1434a. Whether such sentiment is widespread is not clear, particularly since hospitals generally do not segregate medicine by capsule color. Similarly, there is little evidence concerning retail pharmacy resistance to purchasing generic drugs in different colored capsules. See *id.* at 1109a-1110a, 747e-749e. It is difficult, on the present record, to gauge how significant a market barrier such sentiment would be or to assess whether resistance from hospitals, wholesalers or retail pharmacies is substantial enough to render color a functional feature.

III. THE DISTRICT COURT'S JUDGMENT GRANTS OVERLY BROAD AND INAPPROPRIATE RELIEF

If, after remand, it is determined that some form of relief is required, that relief should be carefully tailored to meet the circumstances of this case. See, *e.g.*, *Hartford-Empire Co.* v. *United States*, *supra*, 323 U.S. at 409-410, 423, 431-432; *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 532-533. Since a prohibition on copying even a nonfunctional feature of an article may impede competition or engender added marketing costs, it should be considered as a last resort and imposed only to the extent necessary to allow informed consumer choice. See, *e.g.*, *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 122; *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 532-533.[38]

As this Court has emphasized, "[f]ull disclosure gives the manufacturer all the protection to which he is entitled." *Champion Plug Co.* v. *Sanders*, 331 U.S. 125, 130 (1947). Appropriate labeling or packaging of a product is ordinarily sufficient to avoid consumer confusion, as the Second Circuit previously held in *Bose Corp.* v. *Linear Design Labs, Inc.*, 467 F.2d 304, 309-310 (1972). See *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 119-120; *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 532-533. In this case, the district court found that labeling of the capsules themselves would not be effective because the print necessarily would be too small to be legible to the average consumer. Nevertheless, even assuming a violation of Section 43(a), the injunction granted by the district court is excessive in two respects.

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[38] Because the record fails to support a finding of an intentional violation, the district court's award of money damages and profits should be reversed. 15 U.S.C. 1117; cf. 15 U.S.C. 1114(1)(b). See, *e.g.*, *Champion Plug Co.* v. *Sanders*, 331 U.S. 125, 131-132 (1947); *Metric & Multistandard Components Corp.* v. *Metric's, Inc.*, 635 F.2d 710, 715-716 (8th Cir. 1980); *Carl Zeiss Stiftung* v. *VEB Carl Zeiss Jena*, 433 F.2d 686, 706-708 (2d Cir. 1970), cert. denied, 403 U.S. 905 (1971). See also pages 16-22, *supra*.

First, as noted above, separate consideration must be given to relief in the institutional submarket, where capsule color identity is not likely to preclude informed choice by purchasers. Banning color copying in such a submarket is not necessary. Accurate labeling as to source, placed on the container in which pills are delivered to institutional customers, would be sufficient to satisfy all statutory requirements.

Second, the generic manufacturers should be given the opportunity to propose practical alternative remedies, such as prepackaging their products with their own labels for resale to consumers. See SRI International, *Pharmaceutical Industry Perspectives: A U.S. Generics Breakthrough?* 44, 55-56 (May 1980). Such action would allow generic manufacturers to avail themselves of any legitimate commercial advantages deriving from the capsule color of the brand name manufacturers, while preserving product identification features that are of value both to brand name manufacturers and consumers.

CONCLUSION

The decision of the court of appeals should be reversed and the case remanded for further consideration of respondent's claims under Section 43(a) of the Lanham Act.

Respectfully submitted.

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